

FEDERAL TRADE COMMISSION DECISIONS

**FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2003 TO DECEMBER 31, 2003**

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MEMBERS OF THE FEDERAL TRADE COMMISSION
DURING THE PERIOD JULY 1, 2003 TO DECEMBER 31, 2003

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Took oath of office September 30, 1997.

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ORSON SWINDLE, *Commissioner*
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Took oath of office November 17, 1999.

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Appointed August 28, 1998.

*Resigned, effective August 1, 2003

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Complaint

IN THE MATTER OF

THE LASER VISION INSTITUTE, LLC, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4084; File No. 0223053
Complaint, July 8, 2003--Decision, July 8, 2003*

This consent order, among other things, prohibits Respondents The Laser Vision Institute, LLC, Marco Musa, Max Musa, and Marc'Andrea Musa from representing that LASIK (laser assisted *in situ* keratomileusis) or any other refractive surgery services – that is, any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye) – (1) eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; or (3) eliminate the need for bifocals, unless the claims are substantiated by competent and reliable scientific evidence. The order also requires the respondents to possess and rely on competent and reliable scientific evidence to support any future claims about the benefits, performance, efficacy, or safety of any refractive surgery service. In addition, the order prohibits the respondents from misrepresenting (1) that consumers will receive a free consultation that determines their candidacy for LASIK or any other refractive surgery services; (2) the cost to consumers to have their candidacy for refractive surgery services determined; or (3) the information consumers will receive during a consultation for refractive surgery services.

Participants

For the Commission: *Matthew Daynard, Heather Hipsley,
Mary K. Engle and Carolyn Cox.*

For the Respondents: *Matthew Zifrony, and Tripp Scott, LLC.*

COMPLAINT

The Federal Trade Commission, having reason to believe that The Laser Vision Institute, LLC, a corporation, and Marco Musa, Max Musa, and Marc'Andrea Musa, individually and as officers of the corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

Complaint

1. Respondent The Laser Vision Institute, LLC ("LVI"), is a Florida corporation with its principal office or place of business at 3801 South Congress Avenue, Lake Worth, Florida 33461.
2. Respondent Marco Musa is president of LVI. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of LVI, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of LVI.
3. Respondent Max Musa is the chief executive officer of LVI. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of LVI, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of LVI.
4. Respondent Marc'Andrea Musa is vice-president of LVI. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of LVI, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of LVI.
5. Respondents have advertised, offered for sale, and sold directly to the public refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses. These surgery services include, among others, LASIK (laser assisted *in situ* keratomileusis). In LASIK, a computer-assisted surgical knife, called a microkeratome, is used to cut a flap in the cornea. A hinge is left at one end of the flap. The flap is folded back revealing the stroma, the middle section of the cornea. Pulses from a computer-controlled excimer laser then vaporize a portion of the stroma and the flap is replaced. Excimer lasers and the microkeratome are "devices" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act, and refractive

Complaint

surgery services are “services” within the meaning of Section 12 of the Federal Trade Commission Act.

6. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

7. Respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibits A - D, print advertisements, and Exhibit E, portions of a website located at www.laservisioninstitute.com. These advertisements contain the following statements:

Print Advertising

“FREE YOURSELF from the dependence of glasses and contacts! LASIK Laser Vision Correction...

‘Eliminate your need for reading glasses... I did, and I do surgery with it!’” Dr. Richard Livernois Lasik Surgeon/A Lasik Patient...

Lasik as little as \$499...

The Laser Vision Institute...CALL OR COME BY ANYTIME FOR A FREE CONSULTATION (Exhibit A)

* * *

Change Your Life Forever...

with the miracle of LASIK \$499...

Come see how this miraculous, effective, and simple procedure can eliminate a lifetime of dependence on glasses and contacts in a matter of seconds!

CALL OR COME BY ANYTIME FOR A FREE CONSULTATION (\$50 Value)...

Eliminate your need for bifocals... ‘I did, and I do surgery with it!’” Dr. Richard Livernois Lasik Surgeon/A Lasik Patient (Exhibit B)

* * *

Complaint

**. . . .The Laser Vision Institute...YOU MAY NEVER
NEED CONTACTS OR GLASSES AGAIN!...CALL FOR A
FREE CONSULTATION (Exhibit C)**

* * *

LASIK We can now treat **Farsightedness and
**Astigmatism! If you weren't a candidate before, you might
be one now! CALL OR COME IN ANYTIME FOR A
FREE CONSULTATION** (Exhibit D)**

Web site**Home Page**

[Four- page Flash program coupled with depiction of a woman's face without eyewear] imagine independence from ill-fitting glasses . . . or contact lenses that dry and tear . . . Change the way you look at life . . . get LASIK laser vision correction . . . at convenient locations throughout the US . . . using State of the Art Technology

[A boxed and highlighted link at the top right side of each page states 'Book a FREE Consultation']

about LASIK [page link]

Imagine freedom from your ill-fitting, uncomfortable glasses that constantly fog up. Imagine life without the daily hassle of contact lenses that dry out or tear. Thanks to the Laser Vision Institute, you may say goodbye to glasses or contact lenses. . . .

[A boxed and highlighted link at the top right side of the page states 'Book a FREE Consultation']

how the eye works [page link]

Presbyopia LASIK can correct your distance vision, but you may still need glasses for close-up activities. . . . [p.2 of 2]

Complaint

considerations [page link]

At The Laser Vision Institute we will conduct a thorough evaluation to determine candidacy for LASIK. During your consultation, you will receive a detailed Patient Consent Form that will describe the procedure and the risks in detail. One of our staff members will review the form with you and answer your questions. . . .

[A boxed and highlighted link at the top right side of the page states 'Book a FREE Consultation']

frequently asked questions [page link]

Am I a good candidate?

Requires a comprehensive eye examination by our doctors to know for certain if you are a candidate.

More on considerations > [page link]

[A boxed and highlighted link at the top right side of the page states 'Book a FREE Consultation']

about us: Testimonials [page link]

'...It is so wonderful to be able to go in a store and be able to read labels and price tags. Read the newspaper without glasses...' **Linda Brooks**

[A boxed and highlighted link at the top right side of the first page states 'Book a FREE Consultation'] (Exhibit E)

8. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that LVI's LASIK services:
 - A. Eliminate the need for glasses and contacts for life.
 - B. Eliminate the need for reading glasses.
 - C. Eliminate the need for bifocals.

Complaint

9. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made.

10. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made. Among other reasons, LASIK surgery does not eliminate most peoples' need for reading glasses. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that consumers will receive a free consultation that determines their candidacy for LASIK.

12. In truth and in fact, consumers do not receive a free consultation that determines their candidacy for LASIK. Indeed, consumers receive a free, initial meeting with an LVI representative. At this meeting, consumers receive a quoted price for the procedure based on their prescription and other desired services, and are required to pay a \$300 deposit before the risks and limitations of LASIK are disclosed to them and their candidacy is determined by a health care professional at a future time. The \$300 deposit is non-refundable if, after the consultation, consumers elect not to undergo the procedure. Consumers are refunded \$200 of the deposit if they are later rejected as medical candidates. Therefore, the representation set forth in paragraph 11 was, and is, false or misleading.

13. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Complaint

THEREFORE, the Federal Trade Commission this eighth day of July, 2003, has issued this complaint against respondents.

By the Commission.

“Eliminate your need for reading glasses...”

I did, and I do surgery with it!”

Dr. Richard Livernois
Lasik Surgeon/A Lasik Patient



FR YOU

from the
glasses



LA

The Laser Vision Institute is a division of a privately held company providing patients to eye care for over 14 years.

THE PATIENT AND OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY CANCEL PAYMENT OR BE FINANCED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION OR TREATMENT WHICH IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION OR TREATMENT.

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...complete report on the expertise of this distinguished eye surgeon. ...ational affiliations, are indeed, impressive and his awards too numerous to list. ...his field of refractive surgery since 1981 and has been a Course Director since ...of laser surgery. Recognized both here and abroad as an author and lecturer, he ...e research has been published in a number of famous journals, has lectured ...lephia. ...erved his residency at the prestigious Scheie Eye Institute at the University of ...ed his medical degree from Brown University (1972-1976), where he also did his ...d over 7,000 Lasik procedures, and has had Lasik himself. ...ods: is one of our most experienced and distinguished surgeons. He has

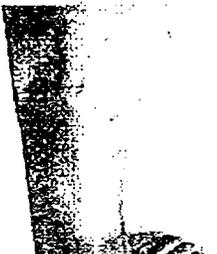
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Dr. Richard Livernois
Lasik Surgeon/A Lasik Patient



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Come see how this miraculous, effective, and simple procedure can eliminate a lifetime of dependence on glasses and contacts in a matter of seconds!

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... of famous journals,
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to utilize your
variable spending
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#7

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15 Minute Painless Vision Correction

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Dr. David O'Day

Dr. David O'Day is one of our most highly trained and experienced corneal and refractive surgeons and is highly regarded for his expertise in the most advanced techniques of LASIK. He completed an ophthalmology residency in Atlanta, Georgia at Emory University School of Medicine and the University of Minnesota, two of the finest programs in the United States.

Dr. O'Day served as Director of the Refractive Surgery Service at University Hospitals of Cleveland and was a member of cornea faculty at Case Western Reserve University School of Medicine in Cleveland, Ohio. He is a well-known teacher, researcher and lecturer who has been featured on television programs, in university seminars and medical journals.

It is Dr. O'Day's reputation, experience in training, credentials that set him apart in the field of LASIK. He has devoted many years of study and training to the development of clinical skills and expertise necessary to perform corneal transplantation, cataract surgery and other complicated anterior segment surgeries. He has performed thousands of complicated microsurgical procedures to restore eyesight and correct potentially blinding problems.

He has used his training and experience to become one of the leading comprehensive corneal-refractive surgeons in the country. Dr. O'Day has been a Fellow of the American Academy of Ophthalmology since 1983. He is featured in the Millennium 2000 edition of Who's Who in America and has been accepted to Who's Who as a Lifetime Member for his many outstanding accomplishments.

*Price may vary according to RX and astigmatism. See center for details. Price per eye.



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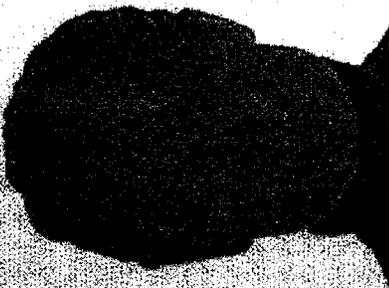
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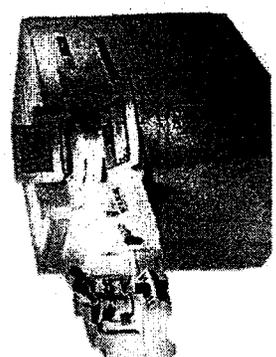
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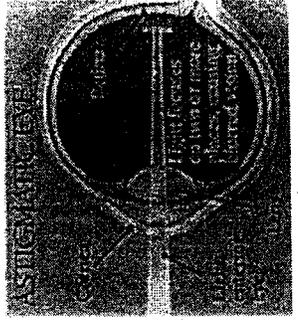
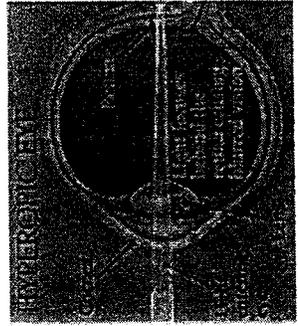
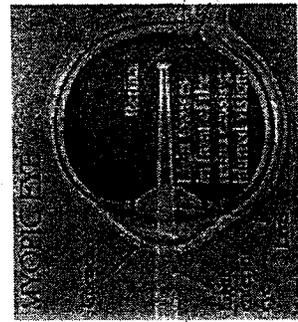
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how the eye works

If you are nearsighted, farsighted, or have an astigmatism, LASIK can reduce and/or eliminate your dependence on glasses or contact lenses.

To better understand LASIK and how the excimer laser can be used in an effort to correct vision problems resulting from refractive error, we have prepared a short overview of how the eye functions.

When light enters the eye it is bent, or refracted, by a clear, strong tissue at the front of the eye called the cornea. The cornea, in effect, acts like a lens to focus incoming light onto the retina at the back of the eye. Refractive errors such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism generally result from an abnormally or irregularly shaped eye.



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Myopia, or nearsightedness, is caused by either an eye shape that is abnormally long or by an excessively steep curvature of the cornea. In nearsightedness, light entering the eye does not focus on the retina as it should, but instead focuses on images at a point in front of the retina. The result of nearsightedness is that distant objects appear

shaped more like a football. The result of astigmatism is that objects are not focused into a single image and vision is distorted or blurry. Both nearsighted and farsighted patients often also suffer from astigmatism.

Presbyopia, or the inability to see close-up objects, occurs normally with age and usually becomes apparent to people in their early forties. Presbyopia results from a change within the eye in which the internal lens loses its ability to focus on close-up objects. LASIK can correct your distance vision, but you may still need glasses for close-up activities.

Vision problems resulting from refractive error (nearsightedness, farsightedness and astigmatism) are routinely corrected either with eyeglasses or contact lenses. The excimer laser can reshape the outer surface of the eye (the cornea) to treat the refractive error and allow the eye to focus properly, thereby reducing or eliminating the need for glasses or contact lenses.

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the LASIK difference

Vision problems resulting from refractive error (nearsightedness, farsightedness, and astigmatism) have long been corrected with eyeglasses or contact lenses. While these methods can produce clear vision, eyeglasses and contact lenses are often considered a hassle.

There are two exciting ways in which the excimer laser can surgically correct vision, utilizing the same principles that allow eyeglasses and contact lenses to produce clear vision: PRK, or Photorefractive Keratectomy, and LASIK, or Laser Assisted In-Situ Keratomileusis.

Before PRK or LASIK, patients receive powerful numbing drops so that they do not feel any pain during the procedure. In PRK, the excimer laser allows the surgeon to reshape the surface of the cornea using pulses of light emitted from the laser.

During LASIK, the surgeon uses a highly sophisticated computer-assisted instrument called a microkeratome to gently create a super-thin flap across the surface of the eye. The powerful numbing drops administered prior to the procedure ensure that patients do not feel any pain during the procedure. The hinged flap is folded back, and the excimer laser is used to reshape the underlying tissue. Following laser treatment, the flap is laid back in place.

Both PRK and LASIK are effective procedures for correcting refractive errors. Although some surgeons

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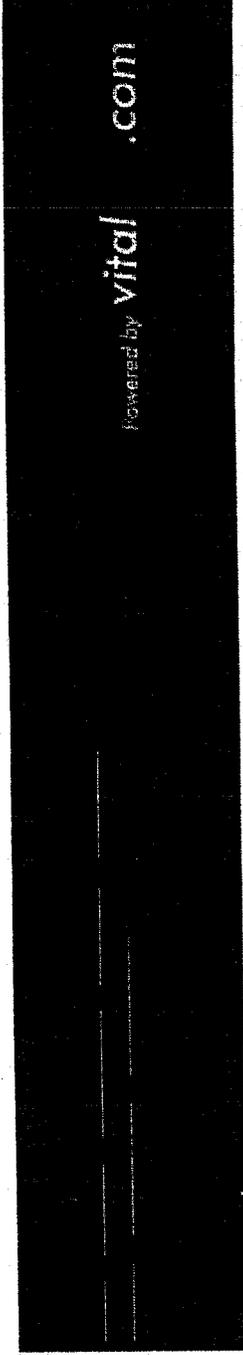
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Procedure Used	Excimer Laser	Excimer Laser
Bowman's Layer	Removed	Left Intact
Post-Op Medication	3-6 months	1-2 weeks
Post-Op Visits (1st Year)	8-10	5
Functional Visual Recovery	3-5 days	12-24 hours
Risk	Low Risk	Low Risk
Risk of Corneal Scarring	1-3%	<1%
Risk of Infection	<1%	<1%

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At The Laser Vision Institute, we will conduct a thorough examination to determine candidacy for LASIK. During your consultation, you will receive a detailed Patient Consent Form that will describe the procedure and the risks in detail. One of our staff members will review the form with you and answer your questions.



LASIK patients must be at least 18 years of age and must not be pregnant or nursing. The conditions listed below may present additional risks or complications and should be discussed with the optometrist or the surgeon prior to the day of the procedure. All are reviewed on a case-by-case basis.

- Unstable refractive error
- Keratitis sicca (advanced dry eyes)
- Severe or poorly controlled glaucoma
- Severe or poorly controlled diabetes
- Recurring ocular herpes simplex
- Cataracts

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What is LASIK?

A laser vision correction procedure that has been performed on millions of people around the world. The Laser Vision offers the most popular form of laser vision correction, LASIK (laser in situ keratomileusis). [More about LASIK >](#)

What is laser vision correction?

Laser vision correction is a precise method of gently reshaping the cornea. Our specially trained ophthalmologist uses a computerized excimer laser to remove a thin layer of tissue from the cornea. This flattens the cornea to the desired correction so the eye can focus properly. [More about LASIK >](#)

What are the most advanced laser vision correction procedures called? PRK (Photorefractive Keratectomy) and LASIK (Laser Assisted In Situ Keratomileusis) [More about LASIK vs. PRK >](#)

Am I a good candidate?

Requires a comprehensive eye examination by our doctors to know for certain if you are a candidate. [More on Considerations >](#)

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What if I wear bifocals?

While LASIK does not deter the natural aging process of the eye (which causes presbyopia), a procedure called monovision can be performed. Monovision is a method of distance vision correction to account for presbyopia. In monovision, the distance vision of the dominant eye is corrected as normal, while the distance vision of the non-dominant eye is slightly under-corrected in order to assist near vision for tasks such as reading. For those requiring the best distance and/or unaided night vision possible, monovision is less desirable. As a guideline, patients from their late 30's to 50 years old should strongly consider slight monovision, while patients over 50 years old should strongly consider full monovision.

[More on Considerations >](#)

Will my insurance cover LASIK?

In most instances, insurance companies consider LASIK "elective" and do not cover the procedure. You should check with your benefits provider to see if they cover LASIK or allow LASIK to be paid for with pre-tax income under a flexible benefits plan. For your convenience, The Laser Vision Institute offers a simple payment plan and accepts all major credit cards.

[More on Payment Options >](#)

Can I have both eyes treated on the same day?

Most patients do elect to have both eyes treated on the same day. The advantages include convenience, less total time away from work and balance in vision. Consult with your physician before you decide. [More on Procedure >](#)

Does the procedure hurt?

Laser vision correction procedures are usually painless. The use of topical anesthesia eye drops numbs the eye. Occasionally, some patients experience slight discomfort a few hours after the procedure. Post-operative discomfort may include slight stinging, excessive tearing and a foreign body sensation. Typically, over-the-counter pain relievers ease this discomfort. A post-operative nap is also recommended to ease discomfort.

[More on Procedure >](#)

For a few weeks, until the eye completely heals, most patients may experience increased glare and halos around bright lights. Patients may also experience some blurriness within the first days after the procedure. Since laser vision correction was first performed in the late eighties, there have been no proven long-term negative effects on the eye's strength.

[More on Considerations >](#)

How long does the whole LASIK procedure take?

The laser operates, on average, less than a minute per eye. Time in the laser room is less than 15 minutes and total time in a Laser Vision Institute facility is generally between two and four hours.

[More about the Procedure Day >](#)

How long will it take for me to achieve stable vision?

Each patient's healing response is different. While most patients will achieve stable vision overnight, others may take a few days or in rare cases, a few weeks. However, most patients report that they return to their normal activity schedule within a day or two.

[More about Post Operative Care >](#)

How soon can I resume normal activities?

Most patients are able to drive and resume normal activities the next day. Patients should not wear eye makeup, swim, get water in their eyes, or expose themselves to dusty or dirty environments for at least three days after surgery. In addition, patients should not rub their eyes for at least ten days after surgery.

[More about Post Operative Care >](#)

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Imagine freedom from your ill-fitting, uncomfortable glasses that constantly fog up.



Imagine life without the daily hassle of contact lenses that dry out or tear.

Thanks to The Laser Vision Institute, you may say goodbye to glasses or contact lenses.

Laser vision correction is a common procedure that has been performed on millions of people around the world. The Laser Vision Institute offers the most popular form of laser vision correction, LASIK (laser assisted in situ keratomileusis).

This area of our web site provides information that can help you to evaluate the LASIK corrective procedure and The Laser Vision Institute's process. Choose from the Topics below:

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The Procedure Day

When you arrive at The Laser Vision Institute on the day of your procedure, you will complete a brief check-in process. You can ask questions at any time. We want you to be as comfortable and relaxed as possible... [More >](#)

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Considerations

LASIK patients must be at least 18 years of age and must not be pregnant or nursing. The conditions listed below may present additional risks or complications and should be discussed... [More >](#)

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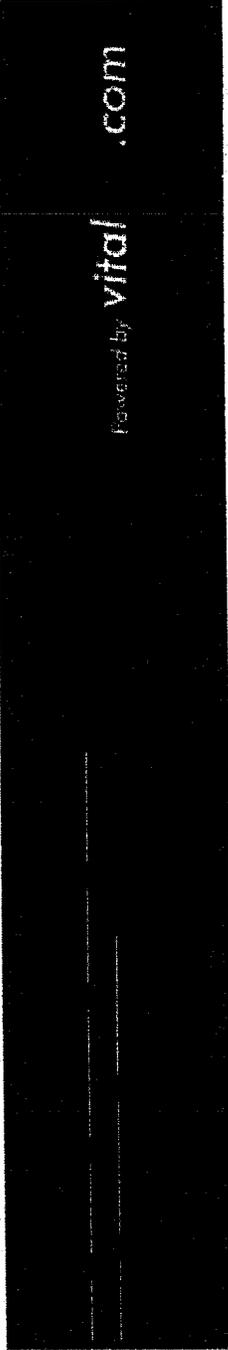
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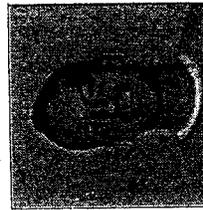
Read what our patients have to say about their results from their LASIK procedure:

"I have not been able to see clearly since age 6, I am now 41 and before the procedure I couldn't read the "E" on the eye chart. I am still waking up every morning thinking I went to sleep with my contacts in!"

Tami Maurer

"The LASIK procedure was great and the results incredible. Everyone was very professional and friendly. I highly recommend the procedure and The Laser Vision Institute."

Dr. Jay Elbrecht



"To anyone who is considering LASIK... Go for it! It's so simple and the results are amazing! It's so worth it. I'd do it again in a heartbeat. I'm so glad I did it!"

Holly Wight

"I have been wearing glasses or contacts for 19 years. When a few friends of mine had LASIK done and had great results, I decided to have it done also. The results were instantaneous; I was able to see when I got off the chair in the



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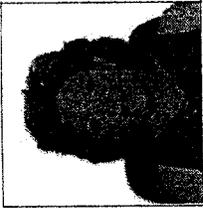
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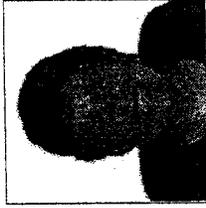
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"After 25 years of wearing contacts and glasses, now I do not need them. Everyone at The Laser Vision Institute is friendly and the procedure only took 10 minutes!"
Lisa Tally

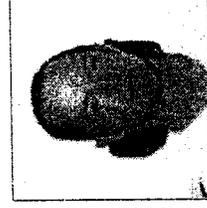


"Best thing I ever did!"
Cindy B. Larsen

"I cannot say enough about my laser eye surgery. It is so wonderful to be able to go in a store and be able to read labels and price tags. Read the newspaper without glasses. Everything is so clear and beautiful. I recommend this procedure to everyone that has to wear glasses, get rid of those things!"
Linda Brooks



"LASIK has allowed me to revisit my youthful years when I could see without glasses, contacts. On a windy day I feel free to walk in the wind clearly."
Thomas Waller



"As a police officer, this procedure has given me more confidence and opportunity than before. It is great to see 20/20, 24 hours a day, seven days a week."
Daniel Floyd

"The LASIK surgery has enhanced my life so very much. The revitalized gift of vision is beyond an expression of words. The entire staff was accommodating, professional, and sincere."
Tami Gir

"Laser vision correction has given me a new



Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorney, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested party pursuant to section 2.34 of its Rules, now in further conformity with the procedure prescribed in section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent The Laser Vision Institute, LLC ("LVI"), is a Florida corporation with its principal office or place of business at 3801 South Congress Avenue, Lake Worth, Florida 33461.

Decision and Order

2. Respondent Marco Musa is the President of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of LVI.
3. Respondent Max Musa is the Chief Executive Officer of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of LVI.
4. Respondent Marc'Andrea Musa is the Vice-President of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of LVI.
5. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondents" shall mean The Laser Vision Institute, LLC, a corporation, its successors and assigns and its officers; Marco Musa, Max Musa, and Marc'Andrea Musa, individually and as officers of the corporation; and each of the above's agents, representatives, and employees.

Decision and Order

2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. "Refractive surgery services" shall mean any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.
4. "Device," shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale of LASIK surgery services or any other refractive surgery services, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such services:

- A. Eliminate the need for glasses and contacts for life;
- B. Eliminate the need for reading glasses; or
- C. Eliminate the need for bifocals, unless, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Decision and Order

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale, of LASIK refractive surgery services or any other refractive surgery services, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the efficacy, safety, performance, or benefits of such services, unless, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale, of LASIK refractive surgery services or any other refractive surgery services, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication:

- A. That consumers will receive a free consultation that determines their candidacy for LASIK or any other refractive surgery services,
- B. The cost to consumers to have their candidacy for refractive surgery services determined, or
- C. The information consumers will receive during a consultation for refractive surgery services.

IV.

Nothing in this order shall prohibit respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

Decision and Order

V.

IT IS FURTHER ORDERED that respondent The Laser Vision Institute, LLC, and its successors and assigns, and respondents Marco Musa, Max Musa, and Marc'Andrea Musa shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondent The Laser Vision Institute, LLC, and its successors and assigns, and respondents Marco Musa, Max Musa, and Marc'Andrea Musa shall deliver a copy of this order to all current and future principals, officers, and directors, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

Decision and Order

VII.

IT IS FURTHER ORDERED that respondent The Laser Vision Institute, LLC., and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that respondents Marco Musa, Max Musa, and Marc'Andrea Musa, for a period of five (5) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their individual current business or employment, or of their individual affiliation with any new business or employment in the eye care industry. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Decision and Order

IX.

IT IS FURTHER ORDERED that respondent The Laser Vision Institute, and its successors and assigns, and respondents Marco Musa, Max Musa, and Marc'Andrea Musa shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

This order will terminate on July 8, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from The Laser Vision Institute, LLC and its principals, Marco Musa, Max Musa, and Marc'Andrea Musa (collectively, "LVI").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged misleading representations about LASIK (laser assisted *in situ* keratomileusis) refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses.

The complaint alleges that LVI failed to substantiate claims that its LASIK surgery services: (1) eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; and (3) eliminate the need for bifocals. Among other reasons, the complaint alleges that LASIK surgery does not eliminate most peoples' need for reading glasses.

According to the FTC complaint, LVI falsely claimed that consumers will receive a free consultation that determines their candidacy for LASIK. In fact, the complaint alleges that consumers receive a free, initial meeting with an LVI representative during which consumers receive a quoted price for the procedure based on their prescription and other desired services, and are required to pay a \$300 deposit before the risks and limitations of LASIK are disclosed to them and their candidacy is determined by a health care professional at a future

Analysis

time. The \$300 deposit is non-refundable if, after the consultation, consumers elect not to undergo the procedure. Consumers are refunded \$200 of the deposit if they are later rejected as medical candidates.

The proposed consent order contains provisions designed to prevent LVI from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; or (3) eliminate the need for bifocals, unless the claims are substantiated by competent and reliable scientific evidence. “Refractive surgery services” are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order prohibits LVI from misrepresenting: (1) that consumers will receive a free consultation that determines their candidacy for LASIK or any other refractive surgery services; (2) the cost to consumers to have their candidacy for refractive surgery services determined; or (3) the information consumers will receive during a consultation for refractive surgery services.

Part IV of the order permits device claims approved by the FDA under any new medical device application.

Parts V and VI of the order require LVI to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, and provide copies of the order to certain of its personnel.

Analysis

Part VII of the order requires the corporate respondent to notify the Commission of changes in corporate structure.

Part VIII of the order requires the individual respondents to notify the Commission of their employment status in the eye care industry.

Part IX of the order requires LVI to file compliance reports with the Commission, and . Part X provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

LCA-VISION, INC. d/b/a LASIKPLUS

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4083; File No. 0223098
Complaint, July 8, 2003--Decision, July 8, 2003*

This consent order, among other things, prohibits Respondent LCA-Vision, Inc., doing business as LasikPlus, from representing that LASIK (laser assisted *in situ* keratomileusis) or any other refractive surgery services – that is, any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye) – (1) eliminate the need for glasses and contacts for life; (2) pose significantly less risk to patients' eye health than wearing glasses or contacts; or (3) eliminate the risk of glare and haloing, unless the claims are substantiated by competent and reliable scientific evidence. The order also requires the respondents to possess and rely on competent and reliable scientific evidence to support any future claims about the benefits, performance, efficacy, or safety of any refractive surgery service.

Participants

For the Commission: *Matthew Daynard, Mary K. Engle and Carolyn Cox.*

For the Respondent: *J. Beckwith Burr, Wilmer, Cutler & Pickering.*

COMPLAINT

The Federal Trade Commission, having reason to believe that LCA-Vision, Inc., a corporation ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent LCA-Vision, Inc. ("LCA") is a Delaware corporation with its principal office or place of business at 7840

Complaint

Montgomery Road, Cincinnati, Ohio 45236. LCA provides refractive surgery services under the brand name *LasikPlus*.

2. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

3. Respondent has advertised, offered for sale, and sold directly to the public refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses. These surgery services include, among others, LASIK (laser assisted *in situ* keratomileusis). In LASIK, a computer-assisted surgical knife, called a microkeratome, is used to cut a flap in the cornea. A hinge is left at one end of the flap. The flap is folded back revealing the stroma, the middle section of the cornea. Pulses from a computer-controlled excimer laser then vaporize a portion of the stroma and the flap is replaced. Excimer lasers and microkeratomes are "devices" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act, and refractive surgery services are "services" within the meaning of Section 12 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused to be disseminated advertisements through various broadcast, print, and outdoor display media, public seminars, and direct mail, including but not necessarily limited to the attached Exhibits A - E. These advertisements contain the following statements:

Television

ANNCR: But now there's a way you could be free from your glasses or contacts forever...[Graphic: LasikPlus logo plus super: A LIFETIME OF BETTER SIGHT...IN JUST MINUTES!] Voice-over: You could enjoy a lifetime of better sight in just minutes with *LasikPlus*. . . . [Exhibit A]

Complaint

Print (Newspapers)

20/20 Vision for \$649! per eye... Now you can afford to get rid of your glasses and contacts for life! So many former eyeglass and contact lens wearers are celebrating the fact that Laser Vision Correction has improved their lives and released them from the on-going hassle and expense of glasses and contacts. . . .[Exhibit B]

Outdoor/Airport

20/20 Vision for \$649* per eye Limited Time Only!
Now you can afford to get rid of your corrective lenses for life! [Exhibit C]

Direct Mail

Fed up with the ongoing expense and hassle of contacts?
LasikPlus lets you throw away your lenses for life!
With LasikPlus laser vision correction, you could have a lifetime of better sight without lenses!. . . . [Exhibit D]

Magazines

Sports Illustrated (Dec. 3, 2001), *U.S. News & World Report* (Dec. 3, 2001), *Time* (Dec. 2001) *Newsweek* (Dec. 2001):

America Abandons Glasses & Contacts
Laser Vision Correction Myths Exposed

Leading Eye Doctors Deal With The Widespread Media Disinformation About Our Nation's Most Popular Elective Surgery. The media have greatly exaggerated and in some cases, completely misrepresented the few problems that can occur with laser vision correction. As with any surgical procedure there are risks. But compared with those associated with contacts and glasses, they are minimal. . . .

Complaint

Over 2 Million People Now Enjoy the Wonders of
Excellent Vision Without the Use of Contacts or
Glasses.

MYTH #1

Laser Vision Correction is Risky

FACTS: Risky? People who wear contact lenses face many more risks from infections or corneal damage. In fact, laser vision correction can eliminate risks often associated with wearing contacts or glasses.

Any problems that may have occurred have usually been the result of people being approved for the procedure when they shouldn't have been. . . .

MYTH #2

Laser Vision Correction Causes Glare & Halos

FACTS: Glare and halos at night are caused when the treatment area does not cover the total area of the dilated pupil. This may create a starburst effect around lights at night. Those providers who offer a choice of the latest FDA approved laser technology can customize the treatment area to accommodate almost any pupil size. This virtually eliminates the risk of glare or haloing.

MYTH #3

Laser Vision Correction Can Cause Blindness

FACTS: Not true...laser vision correction uses a cool beam laser that does not harm tissue. On the other hand, broken lenses from glasses have caused blindness. Contacts have also led to loss of sight from infections or corneal damage. . . .

LasikPlus Vision Center Doctors Believe Your Greatest Safety Assurance Is Knowing All the Facts. . . . If you are

Complaint

interested in enjoying the wonders of 20/20 vision or better without the hassle and expense of contacts or glasses, call LasikPlus. [Exhibit E]

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that LCA's refractive surgery services:

- A. Eliminate the need for glasses and contacts for life.
- B. Pose significantly less risk to patients' eye health than wearing glasses or contacts.
- C. Eliminate the risk of glare and haloming, a starburst effect around lights at night, that can be caused by the LASIK procedure.

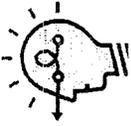
6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.

7. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

8. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this eighth day of July, 2003, has issued this complaint against respondent.

By the Commission.



RESPOND 2

LasikPlus :120 spot
Fourth Draft v.1 & v.2
Draft Date: 11/12/01

MUSIC UP: "STRESSFUL" THEME
OPEN ON GRAPHIC PAGE: [SHOULD BE BREAKDOWN FROM CLIENT]
GLASSES OR CONTACTS WILL COST OVER \$10,000 OVER 10 YEAR
PERIOD. (DISCLAIMER: AVERAGE COST)

ANNOUNCER

(voice-over)

Did you know you could spend over
\$10,000 on glasses and contacts over
the next 10 years?

DISSOLVE TO MONTAGE SEQUENCE OF DOUG/KIM PUTTING ON
GLASSES/TAKING OUT CONTACTS.

ANNOUNCER

(voice-over)

Not to mention all the time, hassle and
discomfort.

MUSIC: CHANGE TO UPBEAT THEME
DISSOLVE TO NEW GRAPHIC PAGE WITH EYE AND ROTATING "SCOPE"
ELEMENT W/SUPER: BE FREE [FROM YOUR GLASSES AND CONTACTS /
FOREVER]

ANNOUNCER

(voice over)

But now there's a way you could be free
from your glasses or contacts forever.

correction provider! Our plusses make the difference.

GRAPHIC: GRAPHIC PAGE WITH "THE LASIKPLUS DIFFERENCE" AS A HEADER AND A ROW OF "PLUSSES" DOWN THE LEFT SIDE. A SUPER COMES IN NEXT TO PLUS #1 - "RESULTS." DISSOLVE TO LIFESTYLE SHOTS (GOLF/WATERSKIING/COMPUTER)

ANNOUNCER

(voice-over)

With LasikPlus, you could enjoy up to 20/20 vision or better! Imagine crisp, clear vision without glasses or contacts!

GRAPHIC: REPRISÉ GRAPHIC PAGE. ADD SUPER TO PLUS #2 - "EXPERIENCE." DISSOLVE TO NEW GRAPHIC - "DECADE OF EXPERIENCE." ADD SUPER OVER VIDEO - "OVER 150,000 SUCCESSFUL PROCEDURES WORLDWIDE."

ANNOUNCER

With over a decade of experience, LasikPlus has performed over 150,000 successful procedures worldwide.

DISSOLVE TO DOUG DURING PROCEDURE. USE CUT TO DOCTOR AND NURSE DURING PROCEDURE.

ANNOUNCER

Each highly trained Master Lasik surgeon has performed an average of 4,000 procedures.

GRAPHIC: REPRISÉ GRAPHIC PAGE. ADD SUPER TO PLUS #3 - "CONTINUUM OF CARE." DISSOLVE TO CALENDAR GRAPHIC THAT SHOWS CONSULTATION, OPERATION, POST-OP CHECK UP AND FOLLOW UP STAGES. END SCENE WITH SHOT OF KIM AND DOCTOR SHAKING HANDS.

ANNOUNCER

LasikPlus is safe, incredibly fast, virtually painless, and patients have described it as a life changing experience.

TESTIMONIALS

REPRISE LIFESTLYE FOOTAGE.

ANNOUNCER

Think about all the things you could do without the hassles of glasses or contacts.

GRAPHIC: REPRISE GRAPHIC PAGE. ADD SUPER TO PLUS #4 -
"VALUE."

GRAPHIC: REPRISE PRICE COMPARISON.

ANNOUNCER

Now think about what you could save. Over the next ten years, you could spend over ten thousand dollars on prescriptions, refills, cleaners, cases and solutions.

GRAPHIC:

ANNOUNCER

But LasikPlus offers you state-of-the-art technology, experience and superior care...and your procedure will be performed by a highly-trained Master Lasik surgeon... all for up to 80% less than what you'd spend on glasses and contacts, and up to 50% less than other Laser Vision Correction providers!

VERSION #1 ENDING

0% FINANCING

ANNOUNCER

And here's another plus: we offer 0% financing, and absolutely no deposit is required.

DISSOLVE BACK TO MAIN PRICE POINT/OFFER CONFIGURATION
SUPERS ON CTA PLATE. CONTINUE TO END.

ANNOUNCER

Find out if laser vision correction is right for you. Call 1-800-123-4567 today to schedule your free consultation. That's 1-800-123-4567. There's no obligation. Set your sights on a lifetime of better vision. Call now!

End

VERSION #2 ENDING

500 CALLERS

ANNOUNCER

Absolutely no deposit is required. And if you're one of our first 500 callers, you can automatically qualify for 0% financing, so call now!

DISSOLVE BACK TO MAIN PRICE POINT/OFFER CONFIGURATION
SUPERS ON CTA PLATE. CONTINUE TO END.

ANNOUNCER

Find out if laser vision correction is right for you. Call 1-800-123-4567 today to schedule your free consultation. That's 1-800-123-4567.

**NOW
OPEN IN
RICHMOND!**

LasikPlus
VISION CENTER

20/20 Vision* for \$649! per eye

Now you can afford
to get rid of your
glasses and
contacts for life!

So many former eyeglass and contact lens wearers are celebrating the fact that Laser Vision Correction has improved their lives and released them from the on-going hassle and expense of glasses and contacts. The only thing that has deterred others from having the procedure is the cost.

*Richmond
Print*

Insertion Dates:

*7/28, 7/29, 8/5
2001*

LasikPlus® Vision Centers have helped thousands of people enjoy lens-free 20/20 vision* or better. Now you can enjoy the benefits of the most advanced technology combined with the expertise of America's leading Ophthalmologists for **thousands less than other leading providers.**

LasikPlus® is proud to be associated with Jason Kaplan, M.D. A board-certified ophthalmologist, Dr. Kaplan has performed over 6,500 Lasik procedures.



Jason Kaplan, M.D.

Call Now to Schedule Your FREE Vision Evaluation

1-888-529-2020

www.lasikplus.com

CONFIDENTIAL

10571 Telegraph Road
Suite 100 • Glen Allen
(Behind Virginia Center Commons)

LCAV B3 0065

Next 500 Patients \$649*
per eye
Limited Time Offer

LasikPlus.

Our Plusesses Make All The Difference

ATIONS: CALIFORNIA • FLORIDA • GEORGIA • ILLINOIS • MARYLAND • MINNESOTA • NEW JERSEY • NEW YORK • NORTH CAROLINA • OHIO • PENNSYLVANIA • VIRGINIA
of our patients now enjoy 20/20 vision. The majority achieve at least 20/40 vision. Results may vary by patient. Additional charge for severe nearsighted prescriptions, all farsighted prescriptions and for contact and toric laser treatment. Price quoted is for LASIK treatment only. Call for details. Price subject to change without notice.

**20/20
Vision
for \$649***

Limited Time Only!

**Now you can
afford to get rid
of your corrective
lenses for life!**



**Free!
5 Minute
Vision
Evaluation**

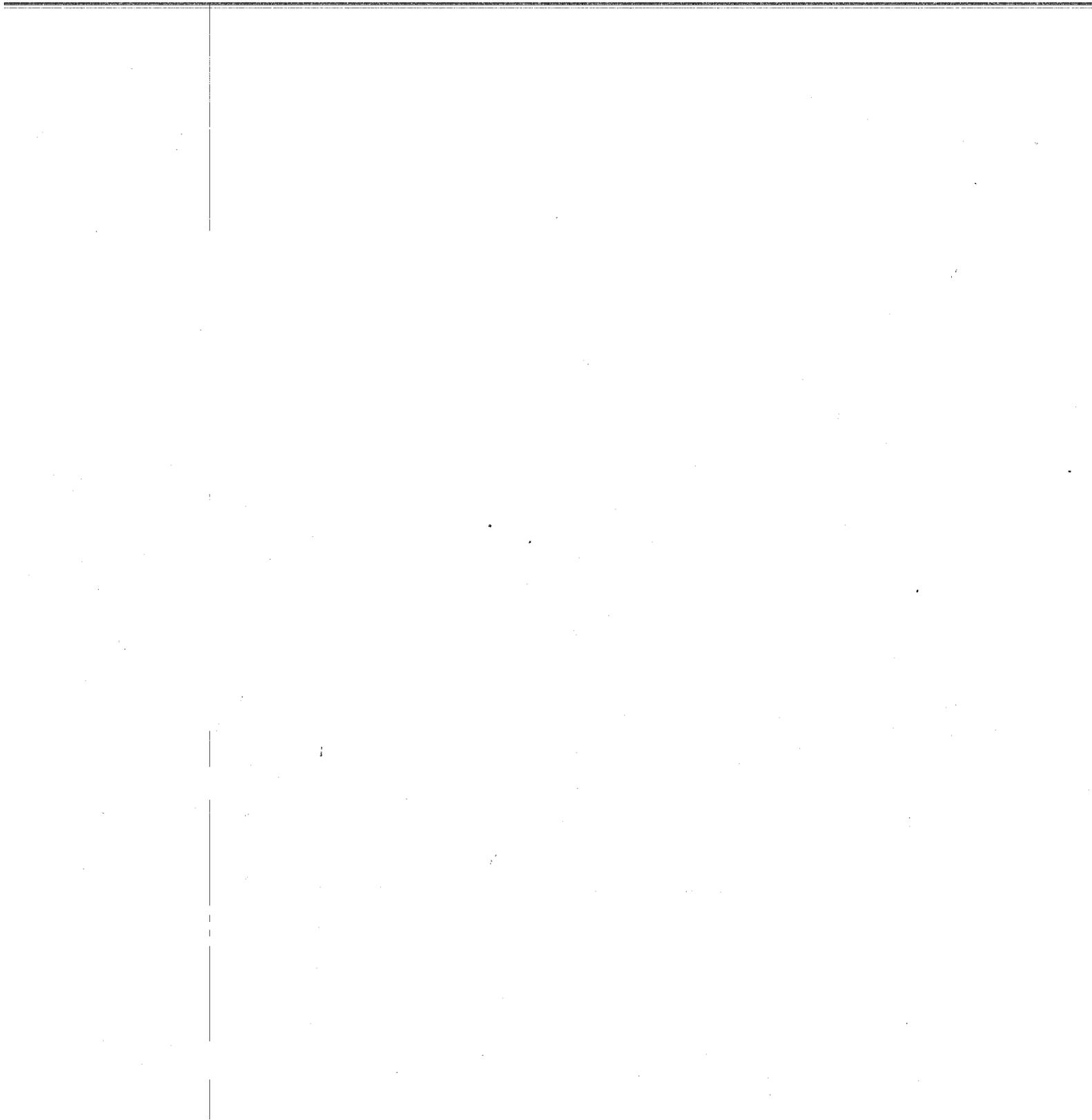
LasikPlus
— VISION + CENTER —



Table Top

Exhibi

CONFIDEN





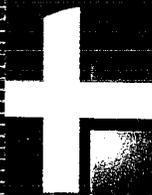
Get up with the
ongoing expense and
hassle of contact?

LasikPlus lets you
throw away your
lenses for life!

First there was the miracle
of Laser Vision Correction,
now there's

LasikPlus

VISION **4** CENTER



**Lowest Price
Guarantee**

We believe everyone should be able to
afford all the plusses of LasikPlus Laser
Vision Correction.



Exhibit D

featuring the *Ultra 20/20* System

- Outstanding Doctors
- Advanced Technology
- Advanced Lasers
- Advanced Computerized Diagnostics and more!

price, anytime – absolutely guaranteed!

Call now for price information
1-888-529-2020

With LasikPlus laser vision correction, you could have a lifetime of better sight without lenses!

Call Now **CONFIDENTIAL**
1-888-529-2020
www.lasikplus.com

to schedule your

**FREE VISION
EVALUATION!**

LasikPlusSM
— VISION CENTER —

You Deserve A Lifetime of Better Sight

Present this card to receive a **FREE Informational Laser Vision Correction Video** during your visit.

LCAV B3 0186

THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION OR TREATMENT.

Laser Vision Correction Myths Exposed

Leading Eye Doctors Deal With The Widespread Media Disinformation About Our Nation's Most Popular Elective Surgery.



CONFIDENTIAL

The media have greatly exaggerated and in some cases, completely misrepresented the few problems that can occur with laser vision correction. As with any surgical procedure there are risks. But compared with those associated with contacts and glasses, they are minimal. That's why a panel of experienced eye doctors have felt it is necessary to deal with the myths that have been created by the media.

Over 2 Million People Now Enjoy the Wonders of Excellent Vision Without the Use of Contacts or Glasses.

MYTH #1

Laser Vision Correction is Risky

FACTS:

Risky? People who wear contact lenses face many more risks from infections or corneal damage. In fact, laser vision correction can eliminate risks often associated with wearing contacts or glasses.

Any problems that may have occurred have usually been the result of people being approved for the procedure when they shouldn't have been.

Reputable laser vision correction providers typically turn away about 20% of people who they evaluate because they are not ideal candidates.

when the treatment area does not cover the total area of the dilated pupil. This may create a starburst effect around lights at night. Those providers who offer a choice of the latest FDA approved laser technology can customize the treatment area to accommodate almost any pupil size. This virtually eliminates the risk of glare or haloing.

MYTH #3

Laser Vision Correction Can Cause Blindness

FACTS:

Not true...laser vision correction uses a cool beam laser that does not harm tissue. On the other hand, broken lenses from glasses have caused blindness. Contacts have

also led to loss of sight from infections or corneal damage.

MYTH #4

The More You Pay, the Better the Treatment

FACTS:

All laser vision providers have board certified doctors and are governed by the FDA so there is no good reason for inflated pricing. Yet many who charge thousands more, do not even offer a choice of advanced lasers (see glare and halos). In spite of their high prices, they are often unable to match the experience and results of doctors charging thousands less.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested party pursuant to section 2.34 of its Rules, now in further conformity with the procedure prescribed in section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent LCA-Vision, Inc. ("LCA"), is a Delaware corporation with its principal office or place of business at 7840

Decision and Order

Montgomery Road, Cincinnati, Ohio 45236. LCA provides refractive surgery services under the name *LasikPlus*.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean LCA-Vision, Inc., a corporation, its successors and assigns and its officers, agents, representatives, and employees.
2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. "Refractive surgery services" shall mean any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.
4. "Device," shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Decision and Order

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale of LASIK surgery services or any other refractive surgery services, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such services:

- A. Eliminate the need for glasses and contacts for life;
- B. Pose significantly less risk to patients' eye health than wearing glasses or contacts; or
- C. Eliminate the risk of glare and haloming,

unless, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale, of any LASIK surgery services or any other refractive surgery services, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy, or safety of any such services, unless, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this order shall prohibit respondent from making any representation for any device that is permitted in labeling for

Decision and Order

such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

V.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, managers, employees, agents, and representatives having responsibilities for developing, contracting for, and/or approving marketing campaigns, marketing materials, advertisements, or claims, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

Decision and Order

VI.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

VIII.

This order will terminate on July 8, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

Decision and Order

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from LCA-Vision, Inc. d/b/a *LasikPlus* (“LCA”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves allegedly misleading representations about LASIK (laser assisted *in situ* keratomileusis) refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses.

According to the FTC complaint, LCA failed to have substantiation for the claims that its LASIK surgery services: (1) eliminate the need for glasses and contacts for life; and (2) pose significantly less risk to patients' eye health than wearing glasses or contacts. Among other reasons, LASIK surgery does not eliminate most peoples' need for reading glasses, and the relative risks of LASIK surgery and wearing contact lenses over time are not readily comparable. The complaint further alleges that LCA did not have substantiation for its claim that its LASIK surgery services eliminate the risk of glare and haloing, a starburst effect around lights at night, that can be caused by the LASIK procedure.

The proposed consent order contains provisions designed to prevent LCA from engaging in similar acts and practices in the future.

Analysis

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) eliminate the need for glasses and contacts for life; (2) pose significantly less risk to patients' eye health than wearing glasses or contacts; or (3) eliminate the risk of glare and haloming, unless the claims are substantiated by competent and reliable scientific evidence. "Refractive surgery services" are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order permits device claims approved by the FDA under any new medical device application.

Parts IV, V, VI, and VII of the order require LCA to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**GROSSMONT ANESTHESIA SERVICES MEDICAL
GROUP, INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4086; File No. 0210006
Complaint, July 11, 2003--Decision, July 11, 2003*

This consent order, among other things, prohibits Respondent Grossmont Anesthesia Services Medical Group, Inc. – a group of approximately 10 anesthesiologists in San Diego County, California, who are also members of the medical staff of Grossmont Hospital in La Mesa, California – from entering into or facilitating agreements between or among medical practices (1) to negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. The order also prohibits the respondent from attempting to engage in – or from encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order.

Participants

For the Commission: *John Wiegand, Kerry O'Brien, Lisa D. Rosenthal, Gwen Fanger, Erika Wodinsky, Jeffrey Klurfeld, D. Bruce Hoffman, Louis Silvia, Mary T. Coleman, and Randi Boorstein.*

For the Respondent: *David Diehl, MD., pro se.*

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that Grossmont Anesthesia Services Medical Group, Inc., a California corporation, (“Respondent” or “GAS”) has violated Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that this proceeding is in the public interest, alleges:

Complaint

PARAGRAPH 1: GAS is a professional corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 5101 Garfield Street, La Mesa, CA 91941. GAS is composed of approximately 10 anesthesiologists.

PARAGRAPH 2: Anesthesia Service Medical Group, Inc. (“ASMG”) is a professional corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 3626 Ruffin Road, San Diego, CA 92123. ASMG employs approximately 180 anesthesiologists.

PARAGRAPH 3: At all times relevant to this Complaint, ASMG and GAS have provided, and do provide, anesthesia services for a fee to patients in San Diego County, California.

PARAGRAPH 4: Except to the extent that competition has been restrained as alleged in this Complaint, ASMG and GAS have competed, and do compete, with each other to provide anesthesia services in San Diego County, California.

PARAGRAPH 5: ASMG and GAS anesthesiologists are, or have been, members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. ASMG and GAS anesthesiologists make up approximately 75 percent of the anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

PARAGRAPH 6: Respondent is, and at all relevant times has been, engaged in commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

PARAGRAPH 7: Respondent is, and at all relevant times has been, a corporation, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Complaint

**DELIVERY OF ANESTHESIA SERVICES IN SAN DIEGO
COUNTY**

PARAGRAPH 8: Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit.

PARAGRAPH 9: In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be “taking call.”

PARAGRAPH 10: Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists “stipends” for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

PARAGRAPH 11: Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

Complaint

PARAGRAPH 12: Grossmont Hospital does not now, and has not in the past, paid its anesthesiologists a stipend for taking call or for rendering services to uninsured emergency room patients.

AGREEMENT TO RESTRAIN TRADE

PARAGRAPH 13: As early as February 2001, ASMG and GAS discussed between themselves a joint strategy to secure stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. As part of these communications, ASMG and GAS discussed stipend amounts that they both would demand from Grossmont Hospital. Eventually, ASMG and GAS agreed on the stipend amount both groups would demand from Grossmont Hospital for taking obstetric call.

PARAGRAPH 14: In July 2001, ASMG sent a formal request to Grossmont Hospital on behalf of ASMG anesthesiologists for a daily obstetric stipend of \$1,000, which was the price ASMG had agreed upon with GAS. ASMG also mentioned that it would be sending the hospital a separate proposal regarding a stipend for the uninsured emergency room patients. Grossmont Hospital rejected ASMG's proposal, and ASMG communicated this rejection to GAS. In response, ASMG and GAS discussed between themselves whether they would reduce the hours for which they would take call. They agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS also agreed to meet with Grossmont Hospital administrators and agreed on a strategy for the meeting.

PARAGRAPH 15: In January 2002, ASMG and GAS met jointly with Grossmont Hospital administrators to discuss their demands for stipends for taking obstetric call and for rendering services to uninsured emergency room patients. At that meeting, ASMG and GAS demanded that the hospital pay them stipends, but the hospital refused. In March 2002, ASMG and GAS again

Complaint

discussed between themselves the hospital's refusal to pay them stipends. ASMG and GAS also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital.

PARAGRAPH 16: Through the acts and practices described above, GAS has agreed, combined, or conspired with ASMG to restrain competition by, among other things, facilitating, negotiating, entering into, and/or implementing agreements between itself and ASMG on fees, quantity of anesthesia services provided, and other competitively significant terms.

PARAGRAPH 17: Respondent's acts and practices described above constitute unfair methods of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. Such acts and practices or their effects are continuing and will continue or recur in the absence of the relief requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eleventh day of July, 2003, issues its Complaint against Respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Grossmont Anesthesia Services Medical Group, Inc., hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Commission staff proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from interested persons pursuant to section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Grossmont Anesthesia Services Medical Group, Inc. is a professional corporation organized, existing, and doing

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business under and by virtue of the laws of the State of California, with its office and principal place of business located at 5101 Garfield Street, La Mesa, CA 91941.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means Grossmont Anesthesia Services Medical Group, Inc., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Grossmont Anesthesia Services Medical Group, Inc., and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- C. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- D. “Medical Practice” means a bona fide, integrated business entity in which Physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one Physician practices medicine.
- E. “Payor” means any Person that pays, or arranges for payment, for all or any part of any Physician services for itself or for any other Person.

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- F. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a Payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- G. “Qualified risk-sharing joint arrangement” means an arrangement to provide Physician services in which:
1. all Physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the Physicians who participate to jointly control costs and improve quality by managing the provision of Physician services, such as risk-sharing involving:
 - a. the provision of Physician services to Payors at a capitated rate,
 - b. the provision of Physician services for a predetermined percentage of premium or revenue from Payors,
 - c. the use of significant financial incentives (e.g., substantial withholds) for Physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by Physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity, or length of treatment, or other factors; and

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2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- H. “Qualified clinically-integrated joint arrangement” means an arrangement to provide Physician services in which:
1. all Physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the Physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondent, directly or indirectly, or through any corporate or other device, in connection with the provision of anesthesia services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Medical Practices:
1. To negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services,

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2. To deal, to refuse to deal, or to threaten to refuse to deal with any Payor of anesthesia services, or
 3. To reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services;
- B. Attempting to engage in any action prohibited by Paragraph II.A. above; and
- C. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraph II.A. and II.B. above.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit any agreement involving, or conduct by, Respondent that is reasonably necessary to form, participate in, or take any other action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail a copy of this Order and the Complaint to:
1. each Physician who participates in Respondent, and
 2. each officer, director, manager, and employee of Respondent;
- B. For a period of three (3) years after the date this Order becomes final, distribute by first-class mail a copy of this Order and the Complaint to:

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3. each Physician who begins participating in Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such participation begins, and
 4. each person who becomes an officer, director, manager, and employee of Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that he or she assumes such responsibility with Respondent;
- C. Within ninety (90) days after the date on which this Order becomes final, file with the Commission a verified written report demonstrating how it has complied and is complying with this Order; and
- D. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

IV.

IT IS FURTHER ORDERED that Respondent shall notify the Commission of any change in its principal address within twenty (20) days of such change in address.

V.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts,

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correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and

- B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, or employees of Respondent in the presence of counsel.

VI.

IT IS FURTHER ORDERED that this Order shall terminate on July 11, 2023.

By the Commission.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a proposed consent order with Grossmont Anesthesia Services Medical Group, Inc. (“GAS” or “Respondent”). The agreement settles charges that Respondent violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements with Anesthesia Service Medical Group, Inc. (“ASMG”) on fees, quantity of anesthesia services provided, and other competitively significant terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

THE COMPLAINT ALLEGATIONS

GAS and ASMG are competing anesthesiology groups that provide anesthesia services for a fee to patients in San Diego County, California. ASMG employs approximately 180 anesthesiologists. GAS is composed of approximately 10 anesthesiologists. GAS and ASMG anesthesiologists are members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. GAS and ASMG anesthesiologists make up approximately 75 percent of the

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anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit. In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be “taking call.”

Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists “stipends” for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

From as early as February 2001 through March 2002, GAS and ASMG discussed between themselves a joint strategy to secure

Analysis

stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. Eventually, GAS and ASMG agreed on the stipend amount both groups would demand from the hospital for taking obstetric call. GAS and ASMG also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital. Furthermore, they agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS ceased this collusive activity only after the Commission contacted them about this conduct. While the Commission's investigation prevented any anticompetitive effects from occurring, this conduct is a naked restraint, which constitutes an unfair method of competition in violation of Section 5 of the FTC Act.

THE PROPOSED CONSENT ORDER

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint while allowing Respondent to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements between or among medical practices: (1) to negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. A "medical practice" is defined as a bona fide, integrated business entity in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph II.B prohibits Respondent from attempting to engage in any action prohibited by Paragraph II.A. Paragraph II.C

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prohibits Respondent from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A and II.B.

Paragraph II contains a proviso that allows Respondent to engage in conduct that is reasonably necessary to the formation or operation of a “qualified risk-sharing joint arrangement” or a “qualified clinically-integrated joint arrangement.” To be a “qualified risk-sharing joint arrangement,” an arrangement must satisfy two conditions. First, all participating providers must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a “qualified clinically-integrated joint arrangement,” an arrangement must satisfy two conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among providers to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

Paragraphs III through V of the proposed order are reporting and compliance provisions. Paragraph VI is a provision “sunsetting” the order after 20 years.

Complaint

IN THE MATTER OF

ANESTHESIA SERVICE MEDICAL GROUP, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4085; File No. 0210006
Complaint, July 11, 2003--Decision, July 11, 2003*

This consent order, among other things, prohibits Respondent Anesthesia Service Medical Group, Inc. – a group of approximately 180 anesthesiologists in San Diego County, California, who are also members of the medical staff of Grossmont Hospital in La Mesa, California – from entering into or facilitating agreements between or among medical practices (1) to negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. The order also prohibits the respondent from attempting to engage in – or from encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order.

Participants

For the Commission: *John Wiegand, Kerry O'Brien, Lisa D. Rosenthal, Gwen Fanger, Erika Wodinsky, Jeffrey Klurfeld, D. Bruce Hoffman, Louis Silvia, Jr., Mary T. Coleman, and Randi Boorstein.*

For the Respondent: *Daniel J. Yakoubian, and Arthur Lerner, Crowell & Moring.*

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that Anesthesia Service Medical Group, Inc., a California corporation, (“Respondent” or “ASMG”) has violated Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that this proceeding is in the public interest, alleges:

Complaint

PARAGRAPH 1: Anesthesia Service Medical Group, Inc. (“ASMG”) is a professional corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 3626 Ruffin Road, San Diego, CA 92123. ASMG employs approximately 180 anesthesiologists.

PARAGRAPH 2: Grossmont Anesthesia Services Medical Group, Inc. (“GAS”) is a professional corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 5101 Garfield Street, La Mesa, CA 91941. GAS is composed of approximately 10 anesthesiologists.

PARAGRAPH 3: At all times relevant to this Complaint, ASMG and GAS have provided, and do provide, anesthesia services for a fee to patients in San Diego County, California.

PARAGRAPH 4: Except to the extent that competition has been restrained as alleged in this Complaint, ASMG and GAS have competed, and do compete, with each other to provide anesthesia services in San Diego County, California.

PARAGRAPH 5: ASMG and GAS anesthesiologists are, or have been, members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. ASMG and GAS anesthesiologists make up approximately 75 percent of the anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

PARAGRAPH 6: Respondent is, and at all relevant times has been, engaged in commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

PARAGRAPH 7: Respondent is, and at all relevant times has been, a corporation, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Complaint

DELIVERY OF ANESTHESIA SERVICES IN SAN DIEGO COUNTY

PARAGRAPH 8: Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit.

PARAGRAPH 9: In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be “taking call.”

PARAGRAPH 10: Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists “stipends” for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

PARAGRAPH 11: Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

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PARAGRAPH 12: Grossmont Hospital does not now, and has not in the past, paid its anesthesiologists a stipend for taking call or for rendering services to uninsured emergency room patients.

AGREEMENT TO RESTRAIN TRADE

PARAGRAPH 13: As early as February 2001, ASMG and GAS discussed between themselves a joint strategy to secure stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. As part of these communications, ASMG and GAS discussed stipend amounts that they both would demand from Grossmont Hospital. Eventually, ASMG and GAS agreed on the stipend amount both groups would demand from Grossmont Hospital for taking obstetric call.

PARAGRAPH 14: In July 2001, ASMG sent a formal request to Grossmont Hospital on behalf of ASMG anesthesiologists for a daily obstetric stipend of \$1,000, which was the price ASMG had agreed upon with GAS. ASMG also mentioned that it would be sending the hospital a separate proposal regarding a stipend for the uninsured emergency room patients. Grossmont Hospital rejected ASMG's proposal, and ASMG communicated this rejection to GAS. In response, ASMG and GAS discussed between themselves whether they would reduce the hours for which they would take call. They agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS also agreed to meet with Grossmont Hospital administrators and agreed on a strategy for the meeting.

PARAGRAPH 15: In January 2002, ASMG and GAS met jointly with Grossmont Hospital administrators to discuss their demands for stipends for taking obstetric call and for rendering services to uninsured emergency room patients. At that meeting, ASMG and GAS demanded that the hospital pay them stipends, but the hospital refused. In March 2002, ASMG and GAS again

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discussed between themselves the hospital's refusal to pay them stipends. ASMG and GAS also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital.

PARAGRAPH 16: Through the acts and practices described above, ASMG has agreed, combined, or conspired with GAS to restrain competition by, among other things, facilitating, negotiating, entering into, and/or implementing agreements between itself and GAS on fees, quantity of anesthesia services provided, and other competitively significant terms.

PARAGRAPH 17: Respondent's acts and practices described above constitute unfair methods of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. Such acts and practices or their effects are continuing and will continue or recur in the absence of the relief requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eleventh day of July, 2003, issues its Complaint against Respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Anesthesia Service Medical Group, Inc., hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Commission staff proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from interested persons pursuant to section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

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1. Respondent Anesthesia Service Medical Group, Inc. is a professional corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 3626 Ruffin Road, San Diego, CA 92123.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means Anesthesia Service Medical Group, Inc., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Anesthesia Service Medical Group, Inc., and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- C. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- D. “Medical Practice” means a bona fide, integrated business entity in which Physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one Physician practices medicine.

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- E. “Payor” means any Person that pays, or arranges for payment, for all or any part of any Physician services for itself or for any other Person.
- F. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a Payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- G. “Qualified risk-sharing joint arrangement” means an arrangement to provide Physician services in which:
1. all Physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the Physicians who participate to jointly control costs and improve quality by managing the provision of Physician services, such as risk-sharing involving:
 - a. the provision of Physician services to Payors at a capitated rate,
 - b. the provision of Physician services for a predetermined percentage of premium or revenue from Payors,
 - c. the use of significant financial incentives (e.g., substantial withholds) for Physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by Physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due

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to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and

2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- H. "Qualified clinically-integrated joint arrangement" means an arrangement to provide Physician services in which:
1. all Physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the Physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondent, directly or indirectly, or through any corporate or other device, in connection with the provision of anesthesia services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Medical Practices:

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1. To negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services,
 2. To deal, to refuse to deal, or to threaten to refuse to deal with any Payor of anesthesia services, or
 3. To reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services;
- B. Attempting to engage in any action prohibited by Paragraph II.A. above; and
- C. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraph II.A. and II.B. above.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit any agreement involving, or conduct by, Respondent that is reasonably necessary to form, participate in, or take any other action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail a copy of this Order and the Complaint to:
1. each Physician who participates in Respondent, and
 2. each officer, director, manager, and employee of Respondent;

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- B. For a period of three (3) years after the date this Order becomes final,
1. Distribute a copy of this Order and the Complaint to:
 - a. each Physician who begins participating in Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such participation begins, and
 - b. each person who becomes an officer, director, manager, and employee of Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that he or she assumes such responsibility with Respondent; and
 2. Secure from each such person a signed and dated statement acknowledging receipt of this Order and the Complaint;
- C. Within ninety (90) days after the date on which this Order becomes final, file with the Commission a verified written report demonstrating how it has complied and is complying with this Order; and
- D. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

IV.

IT IS FURTHER ORDERED that Respondent shall notify the Commission of any change in its principal address within twenty (20) days of such change in address.

Decision and Order

V.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, or employees of Respondent in the presence of counsel.

VI.

IT IS FURTHER ORDERED that this Order shall terminate on July 11, 2023.

By the Commission.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a proposed consent order with Anesthesia Service Medical Group, Inc. (“ASMG” or “Respondent”). The agreement settles charges that Respondent violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements with Grossmont Anesthesia Services Medical Group, Inc. (“GAS”) on fees, quantity of anesthesia services provided, and other competitively significant terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint Allegations

ASMG and GAS are competing anesthesiology groups that provide anesthesia services for a fee to patients in San Diego County, California. ASMG employs approximately 180 anesthesiologists. GAS is composed of approximately 10 anesthesiologists. ASMG and GAS anesthesiologists are members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. ASMG and GAS anesthesiologists make up approximately 75 percent of

Analysis

the anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit. In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be “taking call.”

Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists “stipends” for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

From as early as February 2001 through March 2002, ASMG and GAS discussed between themselves a joint strategy to secure

Analysis

stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. Eventually, ASMG and GAS agreed on the stipend amount both groups would demand from the hospital for taking obstetric call. ASMG and GAS also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital. Furthermore, they agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS ceased this collusive activity only after the Commission contacted them about this conduct. While the Commission's investigation prevented any anticompetitive effects from occurring, this conduct is a naked restraint, which constitutes an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Consent Order

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint while allowing Respondent to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements between or among medical practices: (1) to negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. A "medical practice" is defined as a bona fide, integrated business entity in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph II.B prohibits Respondent from attempting to engage in any action prohibited by Paragraph II.A. Paragraph II.C

Analysis

prohibits Respondent from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A and II.B.

Paragraph II contains a proviso that allows Respondent to engage in conduct that is reasonably necessary to the formation or operation of a “qualified risk-sharing joint arrangement” or a “qualified clinically-integrated joint arrangement.” To be a “qualified risk-sharing joint arrangement,” an arrangement must satisfy two conditions. First, all participating providers must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a “qualified clinically-integrated joint arrangement,” an arrangement must satisfy two conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among providers to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

Paragraphs III through V of the proposed order are reporting and compliance provisions. Paragraph VI is a provision “sunsetting” the order after 20 years.

Complaint

IN THE MATTER OF

SOUTHERN UNION COMPANY, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

*Docket C-4087; File No. 0310068
Complaint, July 16, 2003--Decision, July 16, 2003*

This consent order addresses the acquisition of the Panhandle Eastern Pipeline Company by Respondent Southern Union Company – which distributes and sells natural gas to residential, commercial and industrial customers in Missouri, Pennsylvania, Rhode Island, Massachusetts, and other states, and manages the operation of the Central Pipeline – and American International General (“AIG”), which owns the Central Pipeline – from Respondent CMS Energy Corporation – which engages in the business of oil and gas exploration, natural gas transportation, liquefied natural gas services, independent power production, gas and electricity distribution, and marketing and management services. The order, among other things, requires Respondent Southern Union to terminate its Management Services Agreement with AIG for management of the Central Pipeline. The order also prohibits the respondents from transferring any ownership interest in the Panhandle Pipeline to AIG. In addition, the order prohibits Respondent Southern Union from acquiring any ownership interest in AIG or the Central Pipeline, and prohibits the respondents from transferring any ownership interest in Southern Union, Panhandle or the Panhandle Pipeline to AIG.

Participants

For the Commission: *Dennis F. Johnson, Patricia V. Galvan, Anant Raut, Anne E. Klosterman, Phillip L. Broyles, Susan A. Creighton, Eric D. Rohlck, Daniel P. Ducore, Daniel Gaynor, Louis M. Silvia and Mary T. Coleman.*

For the Respondents: *R. Bruce Beckner and James Moriarty, Fleischman and Walsh, and C. Benjamin Crisman and Brian Mohr, Skadden, Arps, Slate, Meagher & Flom LLP.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“FTC” or “Commission”), having reason to believe that Respondent Southern Union Company (“Southern Union” or “SU”) and Respondent CMS Energy Corporation (“CMS”) have entered into an agreement whereby Southern Union proposes to acquire all of the issued and outstanding shares of Panhandle Eastern Pipeline Company (“Panhandle”) from CMS Gas Transmission Company, a wholly-owned subsidiary of CMS, that such an agreement violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENTS**Southern Union Company**

1. Respondent Southern Union is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One PEI Center, Wilkes-Barre, Pennsylvania 18711.
2. Respondent Southern Union is, and at all times relevant herein has been, engaged either directly or through affiliates in the distribution and sale of natural gas to residential, commercial and industrial customers located in certain states, including Missouri, Pennsylvania, Rhode Island and Massachusetts.
3. Pursuant to an agreement executed November 20, 2002, which continued until it was terminated on May 12, 2003 in order to resolve competitive issues arising from this transaction, respondent Southern Union’s subsidiary, Energy Worx, Inc.

Complaint

(“Energy Worx”), served as the operator and manager of the Central pipeline. The Central pipeline, which transports natural gas to customers in certain Midwestern states, including Kansas and Missouri, is owned by American International Group, Inc. (“AIG”) through its affiliate Southern Star Central Corp. (“Southern Star”).

4. Respondent Southern Union is, and at all times relevant herein has been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affecting commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

CMS Energy Corporation

5. Respondent CMS is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan, with its office and principal place of business located at Fairlane Plaza South, 330 Town Center Drive, Suite 1100, Dearborn, Michigan 48126.
6. Respondent CMS is, and at all times relevant herein has been, engaged either directly or through affiliates in the business of oil and gas exploration, natural gas transportation, liquefied natural gas services, independent power production, gas and electricity distribution, and marketing and management services.
7. Panhandle Eastern Pipeline Company (“Panhandle”), a subsidiary of CMS, owns and operates the Panhandle pipeline, which transports natural gas to customers in certain Midwestern states, including Kansas and Missouri.
8. Respondent CMS is, and at all times relevant herein has been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affecting commerce as

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“commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED TRANSACTION

9. Pursuant to an agreement dated December 21, 2002, and a letter of understanding dated December 20, 2002, Southern Union and affiliates of AIG agreed to acquire all of the capital stock of Panhandle from CMS. The agreement provided that Southern Union would own approximately 77.9%, and affiliates of AIG would own approximately 22.1%, of the equity interest in Panhandle. On May 12, 2003, in order to resolve competitive issues arising from this transaction, Southern Union, Southern Union Panhandle Corp., and CMS Gas Transmission Company entered into an amended and restated stock purchase agreement pursuant to which Southern Union Panhandle Corp., a wholly-owned subsidiary of Southern Union, intends to purchase all of the capital stock of Panhandle from CMS Gas Transmission Company, a wholly-owned subsidiary of CMS. AIG is not a party to the revised transaction and will have no ownership interest in Panhandle. The total value of the transaction is approximately \$1.8 billion.

III. TRADE AND COMMERCE***A. Relevant Product Market***

10. A relevant line of commerce, or product market, in which to analyze the effects of the proposed acquisition is the transportation of natural gas by pipeline. The only way to economically transport commercial quantities of natural gas over significant distances is through large diameter, high pressure pipelines. Buyers of natural gas transportation services could not and would not switch to other means of transportation, or to alternative fuels, if the cost of pipeline transportation of natural gas were to increase by 5% to 10%.

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B. Relevant Geographic Market

11. A relevant section of the country, or geographic market, in which to analyze the proposed acquisition is the Kansas City area, consisting of Cass, Henry, Jackson, Johnson, Lafayette, Pettis and Saline Counties in Missouri, and Anderson, Butler, Chase, Coffey, Franklin, Johnson, Lyon, Marion, Miami and Osage Counties in Kansas. Buyers of natural gas in this geographic market can receive natural gas only from pipelines that travel through or terminate in that geographic market, and cannot economically access natural gas pipelines outside that area.

C. Market Structure

12. Pursuant to a Management Services Agreement with an affiliate of AIG, Southern Union's subsidiary, Energy Worx, served as the operator and manager of the Central pipeline until the parties to that Management Services Agreement terminated it on May 12, 2003, in order to resolve competitive issues arising from this transaction. The Central pipeline transports a significant portion of the natural gas delivered to the relevant geographic market. Pursuant to the Management Services Agreement, Southern Union had managerial and operational control over the business of the Central pipeline, access to confidential competitive information about the Central pipeline, and a financial interest in the Central pipeline. The Management Services Agreement also contemplated that Southern Union would have an equity position in the Central pipeline.
13. The only pipelines that transport natural gas to the relevant geographic market are the Panhandle pipeline, the Central pipeline, and two smaller pipelines that service only part of the western portion of the relevant geographic market. These other two pipelines could not act as a competitive constraint on Central or Panhandle because of operational limitations, capacity constraints, distance factors, and

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related issues. For many buyers of natural gas transportation services in the relevant geographic market, Central and Panhandle are the only viable alternatives.

14. The market for the pipeline transportation of natural gas into the relevant geographic market is highly concentrated and would become significantly more concentrated as a result of the proposed acquisition. As originally proposed, common ownership interest and/or common management and control would exist between the only two alternatives for the transportation of natural gas for many buyers in the relevant geographic market.

D. Entry Conditions

15. Entry into the relevant line of commerce in the relevant section of the country is difficult and would not be timely, likely or sufficient to prevent anticompetitive effects that are likely to result from the proposed acquisition. Building a new pipeline is capital intensive, is subject to significant regulatory constraints, and would require more than two years to accomplish. As a result, new entry would not be able to prevent a 5-10% increase in the price of pipeline transportation of natural gas.

IV. EFFECTS OF THE TRANSACTION

16. The effect of the proposed acquisition, if consummated, may be substantially to lessen competition in the transportation of natural gas by pipeline into the relevant geographic market, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the following ways, among others:
 - a. by eliminating direct competition between the Panhandle pipeline and the Central pipeline;

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- b. by placing the Panhandle pipeline and the Central pipeline under common ownership and/or common management and control;
- c. by increasing the likelihood that unilateral market power would be exercised in the relevant geographic market; and
- d. by increasing the likelihood of, or facilitating, collusion or coordinated interaction in the relevant geographic market,

each of which increases the likelihood that the price of transporting natural gas by pipeline will increase in the relevant geographic market.

V. VIOLATIONS CHARGED

- 17. The proposed acquisition violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and would, if consummated, violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this sixteenth day of July, 2003, issues its complaint against said Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition of Panhandle Eastern Pipeline Company (“Panhandle”) from Respondent CMS Energy Corporation (“CMS”) by Respondent Southern Union Company (“SU”) (SU and CMS hereinafter referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts as set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to section 2.34 of its Rules now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the

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following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Southern Union Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One PEI Center, Wilkes-Barre, Pennsylvania 18711.
2. Respondent CMS Energy Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan, with its office and principal place of business located at Fairlane Plaza South, 330 Town Center Drive, Suite 1100, Dearborn, Michigan 48126.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “SU” means Southern Union Company, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Southern Union Company (including, but not limited to, Missouri Gas Energy, Energy Worx, Inc., and SUPC); and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “CMS” means CMS Energy Corporation, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by CMS Energy Corporation (including, but not limited to, CMS

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Enterprises Company, CMS Gas Transmission Company and Panhandle); and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Acquisition” means the proposed acquisition of Panhandle from CMS by SU as described in the Stock Purchase Agreement.
- E. “Acquisition Date” means the date on which the Acquisition is consummated.
- F. “AIG” means American International Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 70 Pine Street, New York, New York 10270, its joint ventures, subsidiaries, divisions, equity funds, groups and affiliates controlled by American International Group, Inc. (including, but not limited to, AIG Global Investment Corp., AIG Highstar Capital GP, L.P., AIG Highstar Capital L.P., AIG Highstar II Funding Corp., and Southern Star Central Corp.).
- G. “Central Pipeline” means the Central Pipeline acquired by AIG, through AIG Highstar Capital, L.P. and Southern Star Central Corp., from The Williams Companies, that transports natural gas from producing locations in Kansas, Oklahoma, Texas, Wyoming and Colorado to consuming areas in the Midwest.
- H. “Management Services Agreement” means the agreement made and entered into as of November 20, 2002, by and between Southern Star Central Corp. and Energy Worx, Inc., a wholly-owned subsidiary of Southern Union Company, for the operation and management of the

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Central Pipeline by Energy Worx, Inc., and any amendments thereto.

- I. “Non-Public Ownership Interest” means an Ownership Interest that is not registered for sale pursuant to the Securities Act of 1933.
- J. “Ownership Interest” means any stock, share capital, equity, or other interest, or any present or contingent right to such stock, share capital, equity or other interest.
- K. “Panhandle” means Panhandle Eastern Pipeline Company, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 5444 Westheimer Road, Houston, Texas 77056.
- L. “Panhandle Pipeline” means the natural gas pipeline owned by Panhandle that transports natural gas from producing locations in Texas, Oklahoma, and Kansas to consuming areas in the Midwest.
- M. “Person” means any individual, partnership, firm, trust, association, corporation, joint venture, unincorporated organization, equity fund, or other business or governmental entity.
- N. “Respondents” means SU and CMS, individually and collectively, and the Person resulting from the Acquisition.
- O. “Stock Purchase Agreement” means the Amended and Restated Stock Purchase Agreement By and Among CMS Gas Transmission Company, Southern Union Company and Southern Union Panhandle Corp., dated as of May 12, 2003, and any amendments thereto.
- P. “SUPC” means Southern Union Panhandle Corporation, its officers, directors, employees, agents and

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representatives, successors, and assigns; its parents, joint ventures, subsidiaries, divisions, groups and affiliates controlled by Southern Union Panhandle Corporation, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

II.

IT IS FURTHER ORDERED that:

- A. Prior to the Acquisition Date, Respondent SU shall:
 - 1. secure the consent or waiver of AIG for the termination of the Management Services Agreement; and
 - 2. absolutely terminate the Management Services Agreement.
- B. Respondents SU and CMS shall not consummate the Acquisition until the Management Services Agreement has been terminated.
- C. Following the Acquisition Date, Respondent SU shall not, directly or indirectly, operate or manage the Central Pipeline.
- D. Respondent SU shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any Ownership Interest in AIG, including, but not limited to, the Central Pipeline or Southern Star Central Corp.
- E. The purpose of this Paragraph is to ensure that Respondents do not consummate the Acquisition before the Management Services Agreement is terminated, and to ensure that, following the Acquisition, Respondent SU will have no interest in AIG or the Central Pipeline, or any role in managing or operating the Central Pipeline, to

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remedy the lessening of competition from the proposed Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

- A. Respondents SU and CMS shall not sell, give, transfer, or otherwise provide, directly or indirectly, through subsidiaries, partnerships, or otherwise, any Ownership Interest in SU, SUPC, Panhandle, or the Panhandle Pipeline, to AIG.
- B. If either Respondent SU or CMS sells, gives, transfers, or otherwise provides any Non-Public Ownership Interest in SU, SUPC, Panhandle, or the Panhandle Pipeline to any person other than AIG, such Respondent shall transfer such Non-Public Ownership Interest subject to a restriction that prohibits the sale of such Non-Public Ownership Interest to AIG.
- C. The purpose of this Paragraph is to prevent AIG from obtaining an interest in SU, SUPC, Panhandle, or the Panhandle Pipeline, from Respondents, to remedy the lessening of competition from the proposed Acquisition as alleged in the Commission's Complaint.

IV.

IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Respondent SU has fully complied with Paragraph II.A. of this Order and Respondents SU and CMS have fully complied with Paragraph II.B. of this Order, Respondents SU and CMS shall each submit to the Commission a verified written report setting forth in detail the manner

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and form in which they have complied, are complying, and will comply with Paragraph II of this Order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Order and copies of all written communications to and from all persons relating to this Order.

- B. Within thirty (30) days after the date this Order becomes final, and annually for ten (10) years on the anniversary of the date this Order becomes final, Respondents SU and CMS shall submit to the Commission a verified written report setting forth in detail the manner and form in which they have complied, are complying, and will comply with this Order. Respondents SU and CMS shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Order and copies of all written communications to and from all persons relating to this Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United

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States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and
- B. Upon five (5) days' notice and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on July 16, 2013.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment**I. Introduction**

The Federal Trade Commission ("Commission" or "FTC") has made public a draft complaint ("Complaint") alleging that the proposed acquisition of Panhandle Eastern Pipeline Company ("Panhandle") from Respondent CMS Energy Corporation ("CMS") by Respondent Southern Union Company ("Southern Union" or "SU") would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and has entered into an agreement containing consent order ("Agreement Containing Consent Order") pursuant to which Respondents agree to be bound by a proposed consent order ("Proposed Consent Order") that remedies the likely anticompetitive effects arising from the proposed acquisition, as alleged in the Complaint.

II. Description of the Parties and the Transaction

Southern Union, headquartered in Wilkes-Barre, Pennsylvania, is engaged either directly or through affiliates in the distribution and sale of natural gas to residential, commercial and industrial customers located in certain states, including Missouri, Pennsylvania, Rhode Island and Massachusetts. For the fiscal year ended June 30, 2002, SU reported sales of nearly \$1.3 billion and assets of approximately \$2.67 billion.

Pursuant to an agreement executed November 20, 2002, which continued until the agreement was terminated on May 12, 2003, Respondent SU's subsidiary, Energy Worx, Inc. ("Energy Worx"), served as the operator and manager of the Central pipeline. The Central pipeline, which transports natural gas to customers in certain Midwestern states, including Kansas and Missouri, is owned by American International Group, Inc. ("AIG") through its affiliate Southern Star Central Corp. ("Southern Star").

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CMS, headquartered in Dearborn, Michigan, is engaged either directly or through affiliates in the business of oil and gas exploration, natural gas transportation, liquefied natural gas services, independent power production, gas and electricity distribution, and marketing and management services. Panhandle, a subsidiary of CMS, owns and operates the Panhandle pipeline, which transports natural gas to customers in certain Midwestern states, including Kansas and Missouri.

Pursuant to an agreement dated December 21, 2002, and a letter of understanding dated December 20, 2002, Southern Union and affiliates of AIG agreed to acquire all of the capital stock of Panhandle from CMS. The agreement provided that Southern Union would own approximately 77.9%, and affiliates of AIG would own approximately 22.1%, of the equity interest in Panhandle. On May 12, 2003, in order to resolve competitive issues arising from this transaction, Southern Union, Southern Union Panhandle Corp., and CMS Gas Transmission Company entered into an amended and restated stock purchase agreement pursuant to which Southern Union Panhandle Corp., a wholly-owned subsidiary of Southern Union, intends to purchase all of the capital stock of Panhandle from CMS Gas Transmission Company, a wholly-owned subsidiary of CMS. AIG is not a party to the revised transaction and will have no ownership interest in Panhandle. The total value of the transaction is approximately \$1.8 billion.

III. The Complaint

The Complaint alleges that the acquisition of Panhandle from Respondent CMS by Respondent SU would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the transportation of natural gas by pipeline into the Kansas City area. To remedy the alleged anticompetitive effects of the merger, the Proposed Order requires Respondent Southern Union, prior to the proposed acquisition, to terminate the Management Services Agreement with AIG for the

Analysis

management of the Central pipeline. The proposed order also prohibits Southern Union from acquiring an equity position in AIG or the Central Pipeline. In addition, the Proposed Order prohibits Respondents Southern Union and CMS from transferring or otherwise providing any ownership interest in the Panhandle pipeline to AIG.

The Complaint alleges that a relevant line of commerce, or product market, in which to analyze the effects of the proposed acquisition is the transportation of natural gas by pipeline. The only way to economically transport commercial quantities of natural gas over significant distances is through large diameter, high pressure pipelines. Transportation of natural gas by other methods would be unsafe, prohibitively expensive, and otherwise not viable. Buyers of natural gas transportation services could not and would not switch to other means of transportation, or to alternative fuels, if the cost of pipeline transportation of natural gas were to increase by 5% to 10%.

The Complaint further alleges that the proposed transaction would lessen competition in a geographic market in the Kansas City area, consisting of Cass, Henry, Jackson, Johnson, Lafayette, Pettis and Saline Counties in Missouri, and Anderson, Butler, Chase, Coffey, Franklin, Johnson, Lyon, Marion, Miami and Osage Counties in Kansas. Buyers of natural gas in this geographic market can receive natural gas only from pipelines that travel through or terminate in that geographic market, and cannot economically access natural gas pipelines outside that area.

The only pipelines that transport natural gas to the relevant geographic market are the Panhandle pipeline, the Central pipeline, and two smaller pipelines that service only part of the western portion of the relevant geographic market. These other two pipelines could not act as a pricing constraint on Central or Panhandle because of operational limitations, capacity constraints, and distance limitations. As a result, for many buyers of natural gas transportation services in the relevant geographic market, Central and Panhandle are the only viable alternatives.

Analysis

Pursuant to a Management Services Agreement with an affiliate of AIG, Southern Union's subsidiary, Energy Worx, served as the operator and manager of the Central pipeline from November 20, 2002, until the parties to that Management Services Agreement terminated it on May 12, 2003, in order to resolve competitive issues arising from this transaction. The Central pipeline transports a significant portion of the natural gas delivered to the relevant geographic market. Pursuant to the Management Services Agreement, Southern Union had effective control over the business of the Central pipeline, access to confidential competitive information about the Central pipeline, and a financial interest in the Central pipeline. The Management Services Agreement also contemplated that Southern Union would have an equity position in the Central pipeline.

The market for the pipeline transportation of natural gas to the relevant geographic market is highly concentrated and would become significantly more concentrated as a result of the proposed acquisition. As originally proposed, common ownership interest and/or common management and control would exist between the only two alternatives for the transportation of natural gas for many buyers in the relevant geographic market.

Entry into the relevant line of commerce in the relevant section of the country is difficult and would not be timely, likely or sufficient to prevent anticompetitive effects that are likely to result from the proposed acquisition. Building a new pipeline is capital intensive, would involve significant sunk costs, is subject to significant regulatory constraints, and would require more than two years to accomplish. As a result, new entry would not be able to prevent a 5-10% increase in the price of pipeline transportation of natural gas.

The Complaint charges that the proposed acquisition, absent relief, is likely to substantially lessen competition and lead to higher prices for the transportation of natural gas by pipeline to the Kansas City area, by eliminating direct competition between the Panhandle pipeline and the Central pipeline; by placing the

Analysis

Panhandle pipeline and the Central pipeline under common ownership and/or common management and control; by increasing the likelihood that unilateral market power would be exercised in the relevant geographic market; and by increasing the likelihood of, or facilitating, collusion or coordinated interaction in the relevant geographic market.

Resolution of the Competitive Concerns

The Commission has provisionally entered into an Agreement Containing Consent Order with Respondents Southern Union and CMS in settlement of the Complaint. The Agreement Containing Consent Order contemplates that the Commission would issue the Complaint and enter the Proposed Order to remedy the likely anticompetitive effects arising from the proposed acquisition, as alleged in the Complaint.

The parties have agreed to a proposed consent order that requires Southern Union to terminate the Management Services Agreement with AIG for the management of the Central pipeline by Southern Union's wholly-owned subsidiary, Energy Worx, prior to the proposed acquisition. Southern Union and AIG terminated the Management Services Agreement on May 12, 2003. In addition, the Proposed Order prohibits Southern Union and CMS from transferring any ownership interest in the Panhandle pipeline to AIG. The Proposed Order remedies the anticompetitive effects that are likely to result from common ownership and/or common management of the Panhandle pipeline and the Central pipeline in the relevant geographic market.

Paragraph II of the Proposed Order requires Respondents SU and CMS, prior to the acquisition date, to secure the consent or waiver of AIG for the termination of the Management Services Agreement and to absolutely terminate the Management Services Agreement. The Proposed Order explicitly prohibits Southern Union and CMS from consummating the proposed transaction until the agreement has been terminated. Following the acquisition, Respondent SU shall not, directly or indirectly,

Analysis

operate or manage the Central Pipeline. Additionally, the Proposed Order prohibits Respondent SU from acquiring any ownership interest in AIG or the Central pipeline. This paragraph is designed to ensure that Southern Union will not have an ownership interest in AIG, or any role in managing or operating the Central pipeline.

Paragraph III of the Proposed Order prohibits Respondents Southern Union and CMS from transferring any ownership interest in Southern Union, Panhandle or the Panhandle pipeline to AIG. If either Respondent SU or CMS transfers a non-public ownership interest in Southern Union, Panhandle, or the Panhandle Pipeline to someone other than AIG, it must transfer such interest subject to a restriction that prohibits the sale of such interest to AIG. Paragraph III is designed to prevent the parties from providing any interest in the Panhandle pipeline to AIG.

Paragraphs IV through VII contain standard reporting, notice and access provisions. Pursuant to Paragraph IV, Respondents are required to submit to the Commission a verified written report of compliance every thirty days until the Order is complied with and annually for nine years after the first year the Order becomes final. Paragraph V of the Proposed Order provides for notification to the Commission in the event of any corporate changes in the Respondents. Paragraph VI requires that Respondents provide the Commission with access to their facilities and employees for the purposes of determining or securing compliance with the Proposed Order. Finally, Paragraph VII terminates the Order ten years from the date it becomes final.

IV. Opportunity for Public Comment

The Proposed Order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this thirty day comment period will become part of the public record. After thirty (30) days, the Commission will again review the Proposed Order and the comments received and will decide whether it should withdraw

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from the Proposed Order or make final the agreement's Proposed Order.

By accepting the Proposed Order subject to final approval, the Commission anticipates that the competitive problems alleged in the Complaint will be resolved. The purpose of this analysis is to invite public comment on the Proposed Order and to aid the Commission in its determination of whether it should make final the Proposed Order contained in the agreement. This analysis is not intended to constitute an official interpretation of the Proposed Order, nor is it intended to modify the terms of the Proposed Order in any way.

Complaint

IN THE MATTER OF

SPA HEALTH ORGANIZATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4088; File No. 0110197
Complaint, July 17, 2003--Decision, July 17, 2003*

This consent order, among other things, prohibits Respondent SPA Health Organization, doing business as Southwest Physician Associates – a nonprofit corporation that contracts with third-party payors for the provision of medical services on behalf of its approximately 1,000 participating physicians in the eastern part of the Dallas-Fort Worth metropolitan area – from entering into or facilitating agreements among physicians (1) to negotiate on behalf of any physician with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term upon which any physicians deal, or are willing to deal, with any payor; and (4) not to deal individually with any payor or through any arrangement other than the respondent. The order also prohibits the respondent from exchanging or facilitating the transfer of information among physicians concerning any physician’s willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal. In addition, the order prohibits the respondent from attempting to engage in – or from encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order. The order also requires the respondent to terminate, without penalty, payor contracts that it had entered into during the collusive period, at any such payor’s request.

Participants

For the Commission: *Michael Joel Bloom, Susan M. Gelles, Barbara Anthony, D. Bruce Hoffman and Thomas R. Iosso.*

For the Respondent: *Lewis Noonberg and F. Martin Dajani, Piper Rudnick LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that SPA Health Organization (“SPA”),

Complaint

doing business as Southwest Physician Associates (hereinafter “Respondent”), has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

RESPONDENT

PARAGRAPH 1: Respondent is a non-profit corporation, organized, existing, and doing business under and by virtue of the laws of Texas, with its office and principal place of business at 8150 North Central Expressway, Suite 1250, Dallas, Texas 75206.

JURISDICTION

PARAGRAPH 2: At all times relevant to this Complaint, almost all participating practitioners of Respondent were physicians, most of whom were engaged in the business of providing medical services for a fee. Except to the extent that competition has been restrained as alleged herein, participating physicians of Respondent have been, and are now, in competition with each other for the provision of physician services.

PARAGRAPH 3: The general business practices of Respondent, including the acts and practices herein alleged, are in or affecting “commerce” as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH 4: Respondent has been organized in substantial part, and is engaged in substantial activities, for the pecuniary benefit of its participating physicians and is therefore a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

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OVERVIEW OF MARKET AND PHYSICIAN COMPETITION

PARAGRAPH 5: Respondent has approximately 1,000 participating physicians who are licensed to practice medicine in the State of Texas and who are engaged in the business of providing medical services to patients in the eastern part of the Dallas-Fort Worth metropolitan area (hereinafter “Dallas area”).

PARAGRAPH 6: Physicians often contract with third-party payors to establish the terms and conditions, including price terms, under which the physicians will render services to the payors’ subscribers. Physicians entering into such contracts often agree to lower compensation to obtain access to additional patients made available by the payors’ relationship with insureds. These contracts may reduce third-party payors’ costs and enable them to lower the price of insurance, and thereby result in lower medical care costs for subscribers to the payors’ health insurance plans.

PARAGRAPH 7: Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

PARAGRAPH 8: Medicare’s Resource Based Relative Value System (hereinafter “RBRVS”) is a system used by the United States Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. In general, it is the practice of third-party payors in the Dallas area to make contract offers to individual physicians or groups at a fee level specified in the RBRVS, plus a markup based on some percentage of that fee (e.g., “110% of 2001 RBRVS”).

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PARAGRAPH 9: To be competitively marketable in the Dallas area, a third-party payor's health insurance plan must include in its physician network a large number of primary care physicians and specialists who practice in the Dallas area. Many of the primary care physicians and specialists who practice in the Dallas area are participating physicians of Respondent.

PARAGRAPH 10: Competing physicians sometimes use a "messenger" to facilitate the establishment of contracts between themselves and third-party payors in ways that do not constitute or facilitate an unlawful agreement on fees and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians' coordinated responses to contract offers by, for example, electing not to convey a third-party payor's offer to them based on the messenger's opinion on the appropriateness, or lack thereof, of the offer.

RESTRAINT OF TRADE

PARAGRAPH 11: Respondent, acting as a combination of competing physicians, has acted to restrain competition by, among other things:

- A. facilitating, negotiating, entering into, and implementing agreements among its participating physicians on price and other competitively significant terms;
- B. refusing to deal with third-party payors except on collectively agreed-upon terms; and
- C. negotiating uniform fees and other competitively significant terms in third-party payor contracts for Respondent's participating physicians, and refusing to submit third-party payor offers to participating physicians that do not conform to Respondent's standards for contracts.

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FORMATION AND OPERATION OF SPA

PARAGRAPH 12: In 1984 Respondent's predecessor, Southwest Physician Associates, P.A., undertook to educate and assist physicians in contracting with third-party payors for the provision of physician services. That entity, directly or through other organizations which it controlled, entered into contracting activities on behalf of its participating physicians, often pursuant to arrangements in which the physicians bore some financial risk (e.g., through agreements to provide required medical services in return for a capitated fee). In or about 1997, Southwest Physician Associates, P.A. was merged into SPA Health Organization. The purpose and activities of the successor entity, SPA, remained substantially the same.

PARAGRAPH 13: Respondent's risk contracting resulted in significant losses to its participating physicians. Respondent increasingly undertook, on behalf of its participating physicians, to negotiate non-risk contracts with third-party payors – *i.e.*, contracts that do not involve the sharing of financial risk by third-party payors and physicians through arrangements such as fee withholds or capitation – that provide for higher fees and other, more advantageous terms than its individual participating physicians could obtain by negotiating unilaterally with third-party payors. By the spring of 2000, Respondent engaged exclusively in non-risk contracting.

PARAGRAPH 14: Physicians seeking to join Respondent apply for membership and, if qualified, are approved for membership by the SPA Board of Directors. Each physician then typically has signed a "Physician Managed Care Agreement" with SPA, authorizing SPA to negotiate non-risk contracts with third-party payors on his or her behalf.

PARAGRAPH 15: Respondent has negotiated with third-party payors the fees and other terms pursuant to which SPA's participating physicians may render medical care to persons covered by the third-party payors. Following acceptance of a

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contract by Respondent, Respondent has summarized and commented to SPA's participating physicians on the terms of that contract and offered SPA's participating physicians an opportunity to opt in or out of the agreement.

PARAGRAPH 16: Rather than acting simply as a "messenger," as described in Paragraph 10 of this Complaint, Respondent actively bargained with third-party payors, often proposing and counter-proposing fee schedules to be applied, among other terms. To maintain its bargaining power, Respondent has discouraged its participating physicians from entering into unilateral agreements with third-party payors. Respondent has communicated to its participating physicians the general bargaining advantage gained by negotiating with third-party payors collectively through SPA, as well as SPA's determinations that specific fees and other contract terms being offered by third-party payors may be inadequate. Many of Respondent's participating physicians have been unwilling to negotiate with third-party payors apart from SPA, and have communicated that fact to third-party payors seeking to resist SPA's collective demands.

PARAGRAPH 17: Respondent often did not convey to its participating physicians third-party payor offers that SPA deemed deficient, including offers that provided for fees that did not satisfy SPA's Board of Directors. The practice of not conveying third-party payor offers to participating physicians is inconsistent with the messenger model. Respondent instead demanded, and often received, more favorable fee and other contract terms – terms that third-party payors would not have offered to SPA's participating physicians had those physicians engaged in unilateral, rather than collective, negotiations with the third-party payors. Only after the third-party payor acceded to fee and other contract terms acceptable to SPA, would SPA convey the third-party payor's proposed contract to SPA's participating physicians for their consideration.

PARAGRAPH 18: Respondent refused to convey third-party payors' proposed fee and other contract terms to SPA's

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participating physicians even when the payor explicitly requested that it do so. Respondent's discouragement of its participating physicians' contracting directly with third-party payors and its unwillingness to convey third-party payors' proposed contracts to SPA's participating physicians unless and until those offers satisfy SPA's criteria have rendered it less likely and more costly for third-party payors to establish competitive physician networks in the Dallas area without first coming to terms with SPA. As a result, third-party payors often have offered or acceded to Respondent's demands for supracompetitive fees for all of SPA's participating physicians.

LACK OF SIGNIFICANT EFFICIENCIES

PARAGRAPH 19: Since March 2000, Respondent has neither sought nor been willing to enter into agreements with third-party payors in which SPA's participating physicians undertake financial risk-sharing. Further, Respondent's participating physicians have not integrated their practices to create significant potential efficiencies. Respondent's joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

ANTICOMPETITIVE EFFECTS

PARAGRAPH 20: Respondent's actions described in Paragraphs 11 through 18 of this Complaint have had, or have the tendency to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Dallas area in the following ways, among others:

- A. price and other forms of competition among Respondent's participating physicians were unreasonably restrained;
- B. prices for physician services were increased; and
- C. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians.

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PARAGRAPH 21: The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this seventeenth day of July, 2003, issues its Complaint against Respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of SPA Health Organization, doing business as Southwest Physician Associates, hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

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1. SPA Health Organization (“SPA”), doing business as Southwest Physician Associates, is a non-profit corporation, organized, existing, and doing business under and by virtue of the laws of Texas, with its office and principal place of business at 8150 North Central Expressway, Suite 1250, Dallas, Texas 75206. SPA was incorporated by, and its officers and directors are, physicians engaged in the private practice of medicine. It was established and has operated in material part for the pecuniary benefit of physicians associated with SPA.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means SPA Health Organization, doing business as Southwest Physician Associates, its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a Payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)

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- C. “Payor” means any Person that pays, or arranges for payment, for all or any part of any Physician services for itself or for any other Person.
- D. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- E. “Preexisting Contract” means a contract that was in effect prior to the receipt, by all Payors that are parties to such contract, of notice sent by Respondent pursuant to Paragraph III.B. of this Order, of each such Payor’s right to terminate such contract.
- F. “Principal Address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- G. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- H. “Qualified Risk-Sharing Joint Arrangement” means an arrangement to provide Physician services in which:
 - 1. all Physicians who Participate in the arrangement share substantial financial risk through their Participation in the arrangement and thereby create incentives for the Physicians who Participate to jointly control costs and improve quality by managing the provision of Physician services, such as risk-sharing involving:
 - a. the provision of Physician services to Payors at a capitated rate,
 - b. the provision of Physician services for a predetermined percentage of premium or revenue from Payors,

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- c. the use of significant financial incentives (e.g., substantial withholds) for Physicians who Participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by Physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- I. "Qualified Clinically-Integrated Joint Arrangement" means an arrangement to provide Physician services in which:
 1. all Physicians who Participate in the arrangement Participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the Physicians who Participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondent, directly or indirectly, or through any corporate or other device, and all other

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Persons in active concert or participation with Respondent who receive notice of this Decision and Order by personal service or otherwise, in connection with the provision of Physician services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Physicians:
 - 1. to negotiate on behalf of any Physician with any Payor,
 - 2. to deal, refuse to deal, or threaten to refuse to deal with any Payor,
 - 3. regarding any term, condition, or requirement upon which any Physician deals, or is willing to deal, with any Payor, including, but not limited to, price terms, or
 - 4. not to deal individually with any Payor, or not to deal with any Payor through any arrangement other than Respondent.
- B. Exchanging or facilitating in any manner the exchange or transfer of information among Physicians concerning any Physician’s willingness to deal with a Payor, or the terms or conditions, including price terms, on which the Physician is willing to deal;
- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

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PROVIDED, HOWEVER, that nothing in this Paragraph II shall prohibit any agreement involving, or conduct by, Respondent that is reasonably necessary to form, Participate in, or take any other action in furtherance of a Qualified Risk-Sharing Joint Arrangement or a Qualified Clinically-Integrated Joint Arrangement, so long as the arrangement does not restrict the ability, or facilitate the refusal, of Physicians who Participate in it to deal with Payors on an individual basis or through any other arrangement.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail a copy of this Order and the Complaint to:
 1. each Physician who Participates, or has Participated, in Respondent, and
 2. each officer, director, manager, and employee of Respondent;
- B. Within thirty (30) days after the date on which this Order becomes final, send copies of this Order, the Complaint, and the notice specified in Appendix A to this Order, by first-class mail return receipt requested, to the chief executive officer of each Payor that is listed in Appendix B or that contracts with Respondent for the provision of Physician services;
- C. Terminate, without penalty or charge, any Preexisting Contract with any Payor for the provision of Physician services, upon receipt by Respondent of a written request to terminate such contract from any Payor that is a party to the contract or that pays for the Physician services provided through the contract; PROVIDED, HOWEVER, that nothing

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contained herein shall affect the operation of any Preexisting Contract provision pertaining to the continuation of patient care for patients undergoing a course of treatment, or payment therefor, following expiration or termination of the Preexisting Contract;

- D. For a period of three (3) years after the date this Order becomes final:
1. Distribute by first-class mail a copy of this Order and the Complaint to:
 - a. each Physician who begins Participating in Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such Participation begins,
 - b. each Payor that contracts with Respondent for the provision of Physician services, and that did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such Payor enters into such contract, and
 - c. each person who becomes an officer, director, manager, and employee of Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that he or she assumes such responsibility with Respondent; and
 2. Annually publish a copy of this Order and the Complaint in an official annual report or newsletter sent to all Physicians who Participate in Respondent, with such prominence as is given to regularly featured articles;
- E. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any

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other change in Respondent that may affect compliance obligations arising out of this Order; and

- F. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth:
1. in detail, the manner and form in which Respondent has complied and is complying with this Order, including, but not limited to, (a) information sufficient to describe, for each Qualified Risk-Sharing Joint Arrangement established or operated by Respondent, the manner in which the Physicians who Participate in such arrangement share financial risk, and (b) information sufficient to describe, for each Qualified Clinically-Integrated Joint Arrangement established or operated by Respondent, the manner in which the Physicians who Participate in such arrangement have integrated their practices, and
 2. the name, address, and telephone number of each Payor with which Respondent has had any contact during the reporting period.

IV.

IT IS FURTHER ORDERED that Respondent shall notify the Commission of any change in its Principal Address within twenty (20) days of such change in address.

V.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

Decision and Order

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondent, and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

VI.

IT IS FURTHER ORDERED that this Order shall terminate on July 17, 2023.

By the Commission.

Decision and Order

Appendix A
[letterhead of SPA][name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against SPA Health Organization ("SPA"), doing business as Southwest Physician Associates. I call to your attention Paragraph III.C. of the order, which gives you the right to terminate, without penalty or charge, any contracts with SPA that were in effect prior to your receipt of this letter.

Sincerely,

Decision and Order

Appendix B

Accountable Health Plans of America, Inc.
Aetna U.S. Healthcare North Texas, Inc.
Beech Street Corp.
Blue Cross Blue Shield of Texas, A Division of Health Care
Service Corp.
Carrollton-Farmers Branch Independent School District
City of Carrollton
First Health Group Corp.
Harris Select
HealthSmart Preferred Care, Inc.
Humana Health Plan of Texas, Inc.
Lewisville Independent School District
North Texas Healthcare Network
One Health Plan
PacifiCare of Texas, Inc.
Plano Independent School District
ppoNext, Inc.
Private Healthcare Systems, Inc.
ProAmerica Managed Care, Inc.
Provider Networks of America, Inc.
Prudential Healthcare
TML Intergovernmental Employee Benefits Pool
Teacher Retirement System of Texas Coordinated Care
Unicare Life & Health Insurance Company
United Healthcare of Texas, Inc.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with SPA Health Organization, doing business as Southwest Physician Associates (“Respondent” or “SPA”). The agreement settles charges that Respondent violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among SPA members on price and other competitively significant terms; refusing to deal with payors except on collectively agreed-upon terms; and negotiating fees and other competitively significant terms in payor contracts and refusing to submit to members payor offers that do not conform to Respondent’s standards for contracts.

The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final. The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by Respondent that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true. The allegations in the Commission’s proposed complaint are summarized below.

The Complaint

Respondent SPA is a nonprofit corporation that contracts with third-party payors for the provision of medical services on behalf of its approximately 1,000 participating physicians. Respondent is organized and operated to further the pecuniary interests of

Analysis

those physicians, who are licensed to practice medicine in the State of Texas and who are engaged in the business of providing medical services to patients in the eastern part of the Dallas-Fort Worth metropolitan area (hereinafter “Dallas area”).

Physicians often contract with third-party payors, such as insurance companies and preferred provider organizations. The contracts typically establish the price and other terms under which the physicians will render services to the payors’ subscribers. Contracting physicians often agree to accept lower-than-customary compensation from these third-party payors to gain access to additional patients through the payor. Thus, these contracts may reduce payor costs, and may result in lower medical care costs to the payor’s subscribers.

Absent agreements among competing physicians, each competing physician decides for himself or herself whether, and on what price and other terms, the physician will contract with third-party payors to provide medical services to the payors’ subscribers. To be competitively marketable in the Dallas area, a payor must include in its physician network a large number of primary care physicians (“PCPs”) and specialists who practice in the Dallas area. Many of the PCPs and specialists who practice in the Dallas area are members of SPA. Accordingly, many payors concluded that they could not establish a viable physician network in areas in which SPA physicians are concentrated, without including a large number of SPA physicians in that network.

Respondent actively bargained with third-party payors, often proposing and counter-proposing fee schedules to be applied, among other terms. To maintain its bargaining power, SPA has discouraged its participating physicians from entering into unilateral agreements with third-party payors, and it has communicated to its participating physicians SPA’s determinations that specific fees and other contract terms offered by third-party payors may be inadequate. Many of SPA’s participating physicians have been unwilling to negotiate with third-party payors apart from SPA, and have communicated that

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fact to third-party payors seeking to resist SPA's collective demands.

Sometimes a network of competing physicians uses an agent to convey to payors information, obtained from each of its participating physicians individually, about fees and other significant contract terms that the physicians are willing to accept. In other instances, the agent may convey all payor contract offers to network physicians, with each physician then unilaterally deciding whether to accept or reject each offer. These "messenger model" arrangements, which are described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice (see <http://www.ftc.gov/reports/hlth3s.htm>), can facilitate contracting between physicians and payors without fostering agreements among competing physicians on fees and other competitively sensitive terms. Such agreements are likely, however, if the messenger negotiates fees and other competitively significant terms on behalf of the participating physicians, or facilitates the physicians' coordinated responses to contract offers by, for example, electing not to convey a payor's offer to the physicians based on the messenger's opinion of the acceptability or appropriateness of the offer.

Rather than acting simply as a "messenger," Respondent facilitated and implemented agreements among its members on price and other competitively significant contract terms. It actively sought higher prices for its members and often did not convey to its participating physicians third-party payor offers that SPA deemed deficient, including offers that provided for fees that did not satisfy SPA's Board of Directors. SPA instead demanded, and often received, more favorable fee and other contract terms – terms that third-party payors would not have offered to SPA's participating physicians had those physicians engaged in unilateral, rather than collective, negotiations with the payors. Only after the third-party payor acceded to fee and other contract terms acceptable to SPA, would SPA convey the payor's proposed contract to SPA's participating physicians for their consideration.

Analysis

Since July of 1999, SPA and its members have entered only into fee-for-service agreements with payors, pursuant to which SPA and its members did not undertake financial risk-sharing. Further, SPA members have not integrated their practices to create significant potential efficiencies. Respondent's joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration. Instead, the Respondent's acts and practices have restrained trade unreasonably and hindered competition in the provision of physician services in the Dallas area in the following ways, among others: prices and other forms of competition among Respondent's members were unreasonably restrained; prices for physician services were increased; and health plans, employers, and individual consumers were deprived of the benefits of competition among physicians. Thus, Respondent's conduct has harmed patients and other purchasers of medical services by restricting choice of physicians and increasing the prices of medical services.

The Proposed Consent Order

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint while allowing Respondent and member-physicians to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements among physicians: (1) to negotiate on behalf of any physician with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term upon which any physicians deal, or are willing to deal, with any payor; and (4) not to deal individually with any payor or through any arrangement other than SPA.

Paragraph II.B prohibits Respondent from exchanging or facilitating the transfer of information among physicians concerning any physician's willingness to deal with a payor, or the

Analysis

terms or conditions, including price terms, on which the physician is willing to deal.

Paragraph II.C prohibits Respondent from attempting to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D prohibits Respondent from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C.

Paragraph II contains a proviso that allows Respondent to engage in conduct that is reasonably necessary to the formation or operation of a “qualified risk-sharing joint arrangement” or a “qualified clinically-integrated joint arrangement,” so long as the arrangement does not restrict the ability, or facilitate the refusal, of participating physicians to deal with payors on an individual basis or through any other arrangement. To be a “qualified risk-sharing joint arrangement,” an arrangement must satisfy two conditions. First, all participating physicians must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a “qualified clinically-integrated joint arrangement,” an arrangement must also satisfy two conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among physicians to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

As explained previously, the order would bar SPA from encouraging or facilitating agreements among or on behalf of

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otherwise competing physicians as to the terms under which the physicians would provide medical services. SPA's negotiating with a third-party payor of contract terms applicable only to SPA's own proposed performance ordinarily would not encourage or facilitate an agreement among its participating physicians as to the terms under which the physicians would provide medical services. Therefore, a SPA-payor negotiation of terms applicable only to SPA's own proposed performance ordinarily would not be affected by the order. SPA's conduct in such a negotiation may not, however, encourage, facilitate, or conceal an agreement by or on behalf of participating physicians as to the terms upon which they would provide medical services. Thus, for example, the order would not ordinarily preclude SPA's negotiating with third-party payors as to whether, and on what terms, SPA itself would engage in delegated credentialing of physicians on behalf of the payor, undertake specified contract administration activities, maintain specified insurance coverages, or indemnify the payor.

Similarly, the order ordinarily would not affect SPA's communicating to its participating physicians accurate, factual, and objective analyses of proposed third-party payor contract terms, so long as such communication does not encourage, facilitate or conceal a prohibited agreement. SPA may not, however, do so in a manner that directly or by implication suggests that physicians should or should not accept the contract offers or particular terms thereof upon which they would provide medical services. Further, the order ordinarily would not preclude SPA's sharing with a third-party payor SPA's objective analysis of the proposed contract terms prior to communicating that analysis to its participating physicians, provided that SPA informs the payor that SPA will promptly messenger the contract proposal to its participating physicians upon the payor's request, that SPA promptly complies with each such request, and that any such communications by SPA to the payor do not directly or by implication encourage, facilitate, or conceal a prohibited agreement.

Analysis

Paragraphs III.A and III. B require SPA to distribute the complaint and order to its members, payors with which it previously contracted, and specified others. Paragraph III.C requires SPA to terminate, without penalty, payor contracts that it had entered into during the collusive period, at any such payor's request. This provision is intended to eliminate the effects of Respondent's joint price setting. Paragraph III.C also contains a proviso to preserve payor contract provisions defining post-termination obligations relating to continuity of care during a previously begun course of treatment.

The remaining provisions of the proposed order impose complaint and order distribution, reporting, and other compliance-related provisions. For example, Paragraph III. D requires SPA to distribute copies of the complaint and order to incoming SPA physicians, payors that contract with SPA for the provision of physician services, and incoming SPA officers, directors, and employees. Further, Paragraph III.F requires SPA to file periodic reports with the Commission detailing how SPA has complied with the order. Paragraph V. authorizes Commission staff to obtain access to Respondent's records and officers, directors, and employees for the purpose of determining or securing compliance with the order. The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

UNITHER PHARMA, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4089; File No. 0223036
Complaint, July 22, 2003--Decision, July 22, 2003*

This consent order, among other things, prohibits Respondents Unither Pharma, Inc. and United Therapeutics Corporation – which market HeartBar products, chewy food bars and powders enriched with L-Arginine, vitamins, and minerals – from representing that HeartBar (HeartBar, HeartBar Plus, or HeartBar Sport), or any other L-Arginine product used in or marketed for the treatment, cure, or prevention of cardiovascular disease, or the improvement of cardiovascular or vascular function (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk; (3) prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, or reduces the risk of developing cardiovascular disease; (4) reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or (5) improves endurance, circulation, and energy for the general population, unless the claims are substantiated by competent and reliable scientific evidence. The order also requires the respondents to possess competent and reliable scientific evidence to support any future claims about the health benefits, performance, or efficacy of any food, medical food, or dietary supplement used in or marketed for (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function. In addition, the order prohibits the respondents from misrepresenting, with respect to the above products, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research. The order also requires the respondents notify their distributors as to the claims the Commission has challenged and report to the Commission any distributors who continue to make claims that the Commission’s order prohibits.

Participants

For the Commission: *Matthew Daynard, Keith Fentonmiller,
Mary K. Engle and Dennis Murphy.*

For the Respondents: *Daniel Ferrel McInnis, Akin, Gump,
Strauss, Hauer & Feld L.L.P.*

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COMPLAINT

The Federal Trade Commission, having reason to believe that Unither Pharma, Inc., a corporation, and United Therapeutics Corporation, a corporation, have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. a. Respondent Unither Pharma, Inc. (“Unither Pharma”) is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. Unither Pharma is a wholly owned subsidiary of Unither Pharmaceuticals, Inc., which is wholly owned by respondent United Therapeutics Corporation. Unither Pharma markets and sells an L-arginine-based dietary supplement and a purported medical food under the HeartBar brand name. This dietary supplement purportedly treats or prevents cardiovascular disease and/or improves endurance.
- b. Respondent United Therapeutics Corporation (“United Therapeutics”) is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. United Therapeutics participated in the advertising claims challenged herein, including the creation and dissemination of Exhibits H through J.
2. Respondents have advertised, offered for sale, sold and distributed products to the public, including HeartBar, HeartBar Plus, and HeartBar Sport. These products are “foods” and/or “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

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4 Respondents have disseminated or have caused to be disseminated advertisements for HeartBar and HeartBar Plus (collectively “HeartBar”) and HeartBar Sport, including but not necessarily limited to the attached Exhibits A through J. Since at least 1999, advertisements and promotions have appeared on the cookepharma.com and unither.com websites, on product packaging, and/or in print media, such as *Reader’s Digest*, *Modern Maturity*, *Prevention*, *The San Francisco Chronicle*, *The Chicago Sun-Times*, *The Detroit Free Press*, *The Cleveland Plain Dealer*, *The Miami Herald*, and newspaper inserts published by News America Marketing FSI, Inc. HeartBar products are sold in two forms, an edible bar and a powder, which is mixed with water. The bars have sold for approximately \$2 each. According to the product labels, HeartBar and HeartBar Sport contain, among other ingredients, 3 to 6 grams of L-Arginine, soy isoflavones extract, Vitamins A, B-6, B-12, C and E, niacin, folate, iron, and calcium. The advertisements for HeartBar contain the following statements, among others:

Print Advertising:

- A. Today people with heart disease are discovering that taking two HeartBars a day is bringing welcome relief from heart disease symptoms such as ... leg pain - usually within the first two weeks.
One HeartBar a day thereafter may be sufficient to maintain results. ...
Studies show that taking two HeartBars a day ...

* * * *

✓ **Reduce[s] painful symptoms such as angina and leg pain**

* * * *

(Ex. A) (Ex. A is a print advertisement for HeartBar).

B. Here’s what HeartBar can do...

✓ Improve ... heart health

* * * *

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- ✓ Reduce painful symptoms such as ... leg pain
* * * *

(Ex. B) (Ex. B is a print advertisement for HeartBar).

Internet Advertising:

- C. HeartBar® Plus contains 6 grams of arginine per serving, and it has been shown in clinical trials to be effective in ... decreasing angina ... in patients with coronary artery disease. In addition, HeartBar® Plus may be of benefit to selected at-risk population of developing cardiovascular disease.

(Ex. C at 1) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

- D. Eating two **HeartBars** a day ...:
- Reduces painful symptoms of heart disease such as ... leg pain
* * * *
 - Helps improve ability to exercise without pain, discomfort...
* * * *

Results are usually experienced within the first two weeks. After two weeks, one **HeartBar®** may be sufficient to maintain results.

(Ex. D at 1) (Ex. D consists of webpages from the cookepharma.com website dated August 20, 2001).

- E. ...Not to be mistaken for health bar look-alikes, new HeartBar® contains a scientifically proven ingredient to reduce the pain ... associated with vascular disease
* * * *

Fifteen years of scientific research at major institutions reveal that in certain patients the dietary use of the nutritional ingredients in HeartBar®:

- Helps reverse the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart

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* * * *

(Ex. C at 5-6) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

F. How does HeartBar® Work?

... The active ingredients in HeartBar® have been clinically proven, in properly selected patients, to ... increase pain-free exercise performance.

(Ex. C at 7) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

G. How many HeartBars should a consumer eat a day to receive all of the heart and vascular benefits?

Clinical research shows that, for best results, ... significant improvement (66%) in pain free walking distance ... [is] achieved by eating two bars a day.

(Ex. D at 2) (Ex. D consists of webpages from the cookepharma.com website dated August 20, 2001).

H. HeartBar Sport is a line of L-arginine dietary supplements developed from our experience with HeartBar Plus. HeartBar Sport contains 3 grams of arginine per serving, and it has been shown in clinical trials to improve endurance and energy.

(Ex. C at 3) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

I. Who are HeartBar® products for?

* * * *

HeartBar® Sport, the dietary supplement, is intended for older adults or at-risk individuals who wish to maintain good cardiovascular health, as well as benefit from increased energy and endurance.

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(Ex. C at 14-15) (Exhibit F consists of webpages from the cookepharma.com website dated March 26, 2002).

- J. The following testimonials from doctors have appeared on the cookepharma.com website:

1. **Doctor's Corner**

John P. Cooke
Vascular Medicine
Stanford University School of Medicine
Stanford, CA

A Nutritional Approach to a Healthy Endothelium: Case Histories

I have been studying the endothelium for the better part of two decades, first at Mayo where I was trained, then as an Assistant Professor at Harvard, and now as Associate Professor and Director of the NIH-funded Vascular Medicine Program at Stanford. ...

The HeartBar® has now been tested in rigorous, double-blind, placebo-controlled trials and has been shown to improve exercise tolerance and reduce pain in patients with coronary and peripheral arterial disease. Although these clinical trials are very gratifying, what I find even more satisfying are the positive results that I have observed in my own clinic. Here are a few representative anecdotes:

* * * *

A 78 y/o male with intermittent claudication

L. M. is a vigorous 78 year old man who looks younger than his stated age. As an alpine biologist, one of his classes each year involved a month of hiking over the

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heights of Yosemite and King's Canyon. Now, in retirement he is still an outdoorsman, and enjoys outdoor activities with his son.

For the last few years though, he had noticed cramping in his legs after walking up a hill. The discomfort would subside if he stood still for a moment, and then he could go on. But about two years ago, the cramping became a real disability for him. He was tightening up after walking a half-mile, and he could only go that far if he walked slowly. The great outdoors was getting farther away for LM.

He came to my Vascular Medicine clinic at Stanford in the spring of 1999. I prescribed Trental 400 tid. He returned to me 6 weeks later with little improvement. At that point I stopped the Trental and introduced him to the HeartBar. LM began taking two bars daily. It wasn't long before he noticed an improvement, and over time, he continued to improve. At the time of this writing, LM is able to walk faster, without pain, and considers himself unlimited. He is even able to jog a quarter of a mile before he needs to slow down. He's back to the hills, and enjoying the outdoors again with his son.

I hope that you found these anecdotes interesting. I welcome you to send in your own anecdotes regarding your experience with this nutritional therapy.

With warmest regards,
John P. Cooke, MD Ph.D.
Associate Professor and Director
Section of Vascular Medicine
Stanford University School of Medicine

2. [Doctor's Corner](#)

Complaint

Alan S. Bailer
Cardiovascular Diseases
1330 Cottman Ave.
Philadelphia, PA 19111

Patient Success Story

My 77 year old father had a triple coronary artery bypass grafting procedure in 1984. ...

* * * *

I am convinced that, without the HeartBars, my father would have had to undergo another revascularization. Thank you, Cooke Pharma, for this wonderful product.

3. [Doctor's Corner](#)

Marcus S. Kryger
Box 280
Forsyth, MO 65653

PVD Patient Success Stories

- 82 Year old white female with ischemic cardiomyopathy and severe peripheral vascular disease by IMEX scan. Unable to walk 1 block due to leg pain and dyspnea. She was scheduled for femoral artery bypass, but started on HeartBar. Three months later, without surgery or other medical changes, she was walking 2 miles daily and continues to do so, without symptoms, 15 months later.

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* * * *

- 86 Year old white male with CHF due to ischemic cardiomyopathy and severe leg pain on walking over 50 feet. Started on HeartBar BID, no other changes in medical regime. A month later he repaired his roof by himself without any symptoms. He felt well for 4 months then stopped HeartBar. He rapidly became more dyspneic; restarted HeartBar BID with prompt improvement and went deer hunting this past fall.
-

4. Doctor's Corner

Peter Gray
90 South St.
Glens Falls, NY 12801

Great Results—Reducing Angina Episodes, Claudication...

Great results regarding:

* * * *

- Reducing claudication.

I'm now using it with my father for claudication with excellent results.

(Ex. C at 8-13) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

- K. The following testimonials from HeartBar customers have appeared on the cookepharma.com website:

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1. **Mary R. Gompf** from OH

“It was just like my Doctor said. After only 2 weeks of taking the HeartBar, I noticed a dramatic reduction in my ... leg pain. ... Thank you.”

2. **Mr. Barry Dangler** from FL

“...My Cardiologist has taken me off of Imdur for my angina pain now that I'm taking the HeartBar. I feel great.”

3. **Ms. Betty Burke** from CA

“I had severe burning pain in my left leg when I ran up hills. My AB Index, done by Stanford Research, in my left leg was only .5. I read on the Internet that a .4 Index might require amputation. After 2 weeks taking the HeartBar, the burning pain is gone! I can run with no pain. I also don't have any leg pain when playing tennis. I was seen by a vascular surgeon who proclaimed that I had excellent circulation in both legs. HeartBar has really changed my life!”

4. **Mr. Sam Roska** from CA

“I have atherosclerosis in both legs. After 2 angioplasties on my legs, my doctor put me on HeartBar. Further angioplasty presented a 20% risk of amputation. I had been able to walk only up to about 3 minutes before debilitating leg pain forced me to stop. After about a month on the HeartBar, I was able to walk 10 minutes with no pain! I now have much less pain than before.”

5. **Thomas Overbeek** from MI

“I have had leg pains for about 10 years. The pain in my left leg became especially bad in the last 6 months. I could barely walk from the bedroom to the bathroom. I couldn't stand up without pain. Because of my worsening

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condition, I was scheduled for bypass surgery in my leg. My doctor told me my pain would remain, however. But, after 2 weeks taking the HeartBar, the pain in my leg disappeared. It was unbelievable! As scheduled, I went into see my surgeon the day before my surgery; he cancelled the surgery. I haven't felt this good in 10 years. I can walk and climb stairs with no pain now, and can stand for half an hour. ...”

6. **Al White** from MI

“I am almost an Octogenarian (in 6 months)... I have not had to use my Nitro-Stat pills since I started using HeartBars—not a single one. I got my Doctor’s OK first to use the HeartBars.”

(Ex. C at 16-18) (Exhibit F consists of webpages from the cookepharma.com website dated March 26, 2002).

Packaging:

L. Front panel:

HeartBar

Plus

6g L-Arginine per Bar

Clinically Proven Results

* * * *

Complaint

Reduces angina and leg pain

(Ex. C at 2) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002; page 2 depicts packaging for HeartBar Plus).

M. Front panel:

HeartBar

* * * *

Recommended by Doctors for Daily Use

* * * *

• *Helps Reduce... Leg Pain*

* * * *

Back panel:

If you have heart disease, take two
HeartBars
a day to feel a difference within two
weeks.

Eating two HeartBars a day helps ... with the following
results:

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- Reduces painful symptoms of heart disease such as ... leg pain

- Helps improve ability to exercise without pain, discomfort ...

(Ex. E at 1-2; citation omitted) (Ex. E is a copy of the packaging for HeartBar).

N. Front Panel:

HeartBar

Sport

Dietary

Supplement

3g L-Arginine per Serving

Clinically Proven Results

Improves endurance... and energy[]

(Ex. F; citation omitted) (Ex. F is a copy of the front of the packaging for HeartBar Sport from 2002).

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Other Promotions:**O. Is HeartBar® Right for You?**

* * * *

If you are elderly, you might want to consider that as we age, our need for arginine in the diet increases. Eaten in the right amount, arginine can help prevent a variety of age-related vascular problems, including “hardening of the arteries” and plaque formation, and prevent or reverse the symptoms associated with them. ...

(Ex. G at 2) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

P. ...[E]ating HeartBar® products ... can improve your aerobic performance. For these reasons, even those who are not experiencing heart disease or age-related symptoms choose to make HeartBar® part of their daily regimen.

Clinical Research Confirms that HeartBar®

...

* * * *

♥ Relieves painful symptoms such as angina and leg pain.

* * * *

(Ex. G at 3) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

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Q. See Results in Two Weeks!

In clinical studies, after only two weeks of eating two HeartBars® daily, patients showed significant improvement in angina scores[□] In patients suffering from PAD (peripheral artery disease), HeartBar® was shown to significantly improve the ability to walk pain free.[□] After the initial two weeks, one HeartBar® a day may be sufficient to maintain these results.

* * * *

♥ 70% reduction in angina pain

♥ 66% increase in ability to exercise

(Ex. G at 4; citations omitted) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

R. “In my experience, recommending Heart Bar has helped to stop heart disease in my patients.”

Joe Predergast, M.D.

Diabetes Specialist

(Ex. H. at 2; Ex. K is an excerpt from the 2001 United Therapeutics Corporation Annual Report).

S. HeartBar

... Clinical studies conducted by Cooke Pharma have

Complaint

demonstrated the ability of the HeartBar to reduce painful symptoms associated with cardiovascular diseases Randomized, double-blinded clinical studies published in medical journals and presented at the 2000 American Heart Association meeting have shown that the HeartBar works. ...

(Ex. I. at 2; Ex. I is an excerpt from the 2000 United Therapeutics Corporation Annual Report).

**T. United Therapeutics Acquiring Cooke
Pharma,
Expanding into Angina and
Coronary Artery Disease**

Silver Spring, MD and Belmont, CA, December 18, 2000 –

* * * *

...Clinical studies conducted by Cooke Pharma have demonstrated convincingly the ability of the HeartBar to reduce painful symptoms of cardiovascular disease.... ...

(Ex. J at 1; Ex. J is a December 18, 2000, press release from the unitedtherapeutics.com website).

5. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that:

- A. HeartBar substantially decreases leg pain for people with cardiovascular disease;

Complaint

- B. HeartBar reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency;

- C. HeartBar prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, and reduces the risk of developing cardiovascular disease;

- D. HeartBar reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, and medications, such as nitroglycerin, in patients with cardiovascular disease; and

- E. HeartBar Sport improves endurance and energy for the general population.

6. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.

7. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. Several of the representations are not supported by any clinical studies on humans. Other representations are based on results reported in studies that suffer from various flaws, including the failure to account for the placebo effect and extremely small sample sizes, such that the experience of a single or a few subjects account for the benefits purportedly experienced by the active group as a whole. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

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8. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials show that:

- A. HeartBar decreases angina pain, including by as much as 70% within two weeks;
- B. HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease;
- C. HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; and
- D. HeartBar Sport improves endurance and energy for the general population.

9. In truth and in fact, clinical studies, research, and/or trials do not show that:

- A. HeartBar decreases angina pain, including by as much as 70% within two weeks;
- B. HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease;
- C. HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; or
- D. HeartBar Sport improves endurance and energy for the general population.

Therefore, respondents' representations set forth in Paragraph 8, above, were, and are, false or misleading.

10. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Complaint

THEREFORE, the Federal Trade Commission this twenty-second day of July, 2003, has issued this complaint against respondents.

By the Commission.

FREE Help for Heart Disease Sufferers

Get one HeartBar® FREE for EVERY HeartBar You Buy! Or save \$10.00 on a 16-bar carton.

Ask your doctor about taking two HeartBars daily. It can start making a big difference in just two weeks.



For more information about HeartBar or to order directly from us, call toll free (888) 808-6838 or visit our website at www.cookepharma.com. Use under the supervision of a physician. Ask your pharmacist.

Today people with heart disease are discovering that taking two HeartBars a day is bringing welcome relief from heart disease symptoms such as fatigue, chest pain, and leg pain – usually within the first two weeks. One HeartBar a day thereafter may be sufficient to maintain results.

What people are saying about HeartBar...

"I haven't felt this good in 10 years. I can walk and climb stairs with no pain now... My energy level is also up and I can't wait to get out and do things." – Thomas O., MI

"After taking two HeartBars a day for two weeks, the discomfort in my chest is gone... I'm not afraid to walk alone any more. It's sensational! I'm full of energy." – Mary S., PA

"Several months ago, I was introduced to HeartBars by my cardiologist. I am convinced that this product has greatly improved my quality of life." – Mary Ann D., CA

Visit our web site at www.cookepharma.com to read what more people are saying.

HeartBar's exclusive formula is based on the science that won the 1998 Nobel prize in medicine. It is the result of ten years of clinical research at America's leading medical institutions. Studies show that taking two HeartBars a day helps open blood vessels and improves circulation to:

- ✓ Help you feel more active and energetic
- ✓ Reduce painful symptoms such as angina and leg pain
- ✓ Improve your tolerance for activity, so you can do more of the things you've always enjoyed

If you have heart disease or a family history of heart disease, ask your doctor about HeartBar, the only medical food for the dietary management of heart and vascular disease. And use the valuable coupons below to try HeartBar and feel the difference for yourself.

Available at these and other fine pharmacies:

If your pharmacy has run out of HeartBar and you'd like to take advantage of this free offer, you can purchase HeartBar directly from us: 1) By calling toll-free: 1-888-808-6838 2) By visiting our web site at www.cookepharma.com.

Recommended by thousands of cardiologists for relief of heart disease symptoms.

MANUFACTURER COUPON | EXPIRATION DATE 06/30/01

FREE HeartBar®

Get one HeartBar FREE for EVERY HeartBar you buy!

Use under the supervision of a physician.
Available only at pharmacies.



DISCLAIMER: This coupon good only on purchase of product indicated. Any other use constitutes fraud. Limit one coupon per purchase. Redeemable for nearest Cash Value purchase of one HeartBar. Void if black, scratched or otherwise tampered with. Consumer must pay sales tax. ©2001 Cooke Pharma, Inc. All trademarks are the property of the respective owners. Cash value 1/10th off. Coupon may not be combined or duplicated. Cash value 1/10th off by Cooke Pharma, Inc. P.O. Box 6, Belmont, CA 94602.



MANUFACTURER COUPON | EXPIRATION DATE 06/30/01

SAVE \$10.00

On a 16-bar carton of HeartBar®!

Use under the supervision of a physician.
Available only at pharmacies.



DISCLAIMER: This coupon good only on purchase of product indicated. Any other use constitutes fraud. Limit one coupon per purchase. Redeemable for nearest Cash Value purchase of one 16-bar carton of HeartBar. Void if black, scratched or otherwise tampered with. Consumer must pay sales tax. ©2001 Cooke Pharma, Inc. All trademarks are the property of the respective owners. Cash value 1/10th off. Coupon may not be combined or duplicated. Cash value 1/10th off by Cooke Pharma, Inc. P.O. Box 6, Belmont, CA 94602.



Ex. A

If you have heart disease or are at risk for heart disease...

Free HeartBar® Samples! Call 1-888-808-6838.



Use under the supervision of a physician

If any of these describe you...

- ✓ Diagnosed with heart disease
- ✓ High blood pressure
- ✓ Smoker
- ✓ Estrogen deficiency
- ✓ High cholesterol
- ✓ Weight problem (obesity)
- ✓ Diabetes
- ✓ Family history of heart disease

Here's what HeartBar can do...

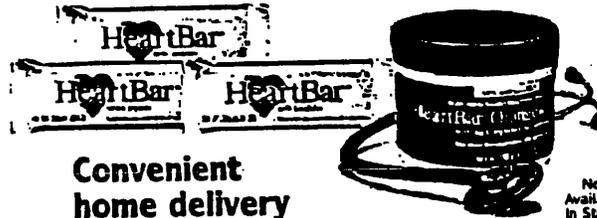
- ✓ Improve circulation and heart health
- ✓ Help you feel more active and energetic
- ✓ Reduce painful symptoms such as angina and leg pain
- ✓ Improve your stamina, so that you can do more of the things you've always enjoyed

Based on Nobel Prize winning science

- Exclusive, patented formula based on the science that won the 1998 Nobel Prize in medicine
- The result of 15 years of clinical research at America's leading medical institutions
- The only medical food for the dietary management of heart and vascular disease
- Recommended by thousands of cardiologists

Delicious new choices

- New low-calorie HeartBar Orange Drink mix (only 40 calories per serving)
- New great tasting HeartBar flavors



Not Available in Stores

Convenient home delivery

- To order, simply call the toll-free number below or visit our web site at www.heartbar.net
- Your order sent via Priority Mail
- This is now the easiest and only way to get HeartBar



**For your free samples,
to order HeartBar, or talk with a
HeartBar Counselor, call toll-free:**

1-888-808-6838

Or visit our web site at www.heartbar.net

Answering America's call for improved heart health

Unither Pharma - HeartBar® Plus, Medical Foods

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HeartBar® Plus - Medical Food



The HeartBar® Plus Product Line - Six Delicious Flavored Bars and an Orange-Flavored Powdered-Drink.

HeartBar® Plus is a line of L-arginine-based medical foods, clinically proven to be safe and effective in the dietary management of people with or at risk of developing cardiovascular disease. It is the first medical food to be listed in the Physician's Desk Reference.

HeartBar® Plus contains 6 grams of arginine per serving, and it has been shown in clinical trials to be effective in enhancing the exercise capacity while decreasing angina while improving the quality of life in patients with coronary artery disease. In addition, HeartBar® Plus may be of benefit to selected at-risk population of developing cardiovascular disease.

Normal dietary sources of L-arginine include nuts, red meat, and seafood; they are usually high in fat content, not desirable for daily consumption by patients with heart disease.

HeartBar® Plus is a convenient dietary source of L-arginine, suitable for daily consumption. For example, a single serving of HeartBar® Plus contains 6 g of L-arginine, which is equivalent to consuming three steaks, or two lobsters, or twelve 500 mg

Unither Pharma - HeartBar® Plus, Medical Foods

arginine plus.

Cardiovascular disease is a serious condition. Patients should not undertake any type of self-diagnoses or self-treatment without the active supervision of a physician. Heartbar® Plus is a medical food, not a conventional food, and is intended for use by patients who are under the care of a physician.



If you have any questions, please feel free to contact us.

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U.S. Pat. & TM Off.

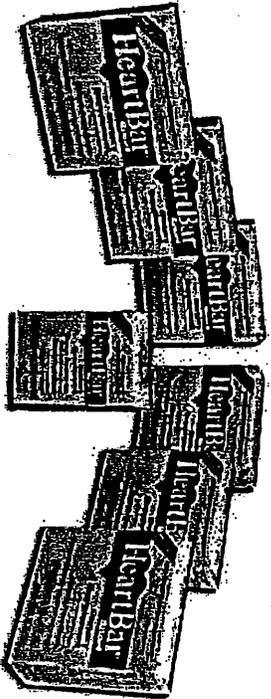
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HeartBar® Sport - Dietary Supplement



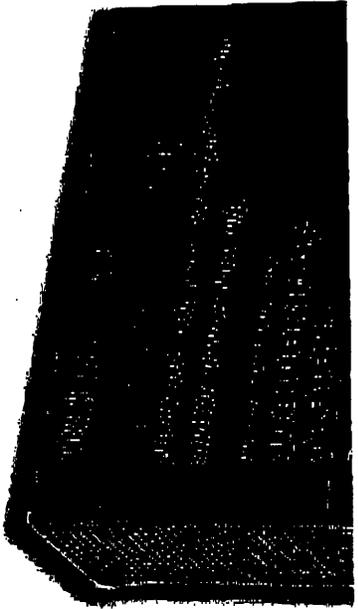
The HeartBar Sport® Product Line - Six Delicious Flavored Bars and an Orange-Flavored Powdered-Drink.

HeartBar Sport is a line of L-arginine dietary supplements developed from our experience with HeartBar Plus. HeartBar Sport contains 3 grams of arginine per serving, and it has been shown in clinical trials to improve endurance and energy.

Millions of Americans are looking for ways to remain fit and healthy for their entire lifetime, and age should not be a barrier to living a full and productive life. Adding HeartBar Sport to your diet may help you lead a more active lifestyle.



Unither Pharma - Heartbar® Sport, Dietary Supplements



If you have any questions, please feel free to contact us.

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<ul style="list-style-type: none">• hot dogs, fatty red meats• butter, egg yolks, and cheese• organ meats like liver, sweetbreads, kidney, and brain• whole milk, cream, and ice cream	<ul style="list-style-type: none">• margarine, and lard• baked goods made with egg yolks and saturated fats• saturated oils like coconut, palm, and palm kernel oil• fried foods
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Certain vitamins have been shown to be beneficial when included in a healthy diet. Antioxidants which are found in vegetables and fruit may reduce the chance of having a heart attack. They work by preventing the damaging effects of free radicals, which can damage cells and cause cholesterol buildup. Niacin, when taken in high doses, lowers triglycerides (fat) and cholesterol as it raises the levels of high-density lipoprotein (HDL). HDL attacks themselves to excess cholesterol in the lining of the blood vessels and pass it out of the body. Finally, there's folic acid. This lowers homocysteine (an amino acid) levels in the blood, which may be a factor in clogging arteries. Folic acid should be taken along with vitamin B12.

Heart Bar™ raises the bar on the dietary management of cardiovascular disease

HeartBar® is the first medical food intended for the dietary management of cardiovascular disease. The US Food and Drug Administration (FDA) has defined a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." [21 U.S.C. § 360e(b)(3)]. It is intended for use under the supervision of a physician.

While this new category of dietary management of cardiovascular disease is very exciting to the medical community, the specifics about new HeartBar® are even more so. Not to be mistaken for health bar snack-slikes, new HeartBar® contains a scientifically

proven ingredient to reduce the pain and fatigue associated with vascular disease, helping patients feel better and become more active after only 2 weeks. How can new HeartBar® do all that? Here's how:

HeartBar® contains a patented formulation designed to increase the body's production of nitric oxide. Research has shown that many patients with heart disease have deficient levels of nitric oxide. The body uses nitric oxide to dilate or widen the blood vessels and allow blood to flow more freely. Nitric oxide also helps prevent cholesterol and platelets from sticking to the blood vessels' walls, which would further inhibit free blood flow.

Fifteen years of scientific research at major institutions reveal that in certain patients the dietary use of the nutritional ingredients in HeartBar®:

- Helps reverse the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart
- Promotes better circulation for better heart health
- Restores blood vessel function for those at risk for or with heart disease

Daily use of this chewy, delicious HeartBar® may be able to help you take a bite out of the painful and life-limiting symptoms of cardiovascular disease. Patients may also benefit from its many other nutrients, which include antioxidants like [such as] vitamins C, E, B6, and B12, as well as potassium, folic acid, niacin, and fiber.

Ask your doctor whether adding HeartBar® to your diet can raise the bar for your cardiovascular health.

If you have any questions or want more information about cardiovascular health, talk with your doctor or health care professional. This general information on cardiovascular disease presented was adapted from information presented by the American Heart Association (AHA) and American Dietetic Association (ADA).

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their arginine from red meats, which is not a desirable source of L-arginine.

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How does HeartBar® Work?

HeartBar® is based on a unique biological marker (indicator). Rather than using high cholesterol as a biological marker of the development of atherosclerosis, Unither has developed a new approach measuring the endothelial production of nitric oxide. Endothelial nitric oxide production is often reduced in people with cardiovascular and peripheral arterial disease as well as those with risk factors for these diseases. The active ingredients in HeartBar® have been clinically proven, in properly selected patients, to restore nitric oxide production, improve vascular function and increase pain-free exercise performance. HeartBar® Plus, the medical food, is intended for use under the supervision of a physician.

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Why can't patients just take an L-arginine pill?

Heart disease patients and healthy individuals CAN take arginine supplement pills, but taking arginine pills are not as convenient as taking a single serving of the deliciously-flavored HeartBar® product. For example, arginine pills usually contain 500 to 750 mg of L-arginine, and a single serving of HeartBar® Plus contains as much L-arginine as twelve 500 mg arginine pills (see table below.) As you can see, HeartBar® products are a more convenient supplemental dietary source of L-arginine.

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Doctor's Corner

John P. Cooke
Vascular Medicine
Stanford University School of Medicine
Stanford, CA

A Nutritional Approach to a Healthy Endothelium: Case Histories

I have been studying the endothelium for the better part of two decades, first at Mayo where I was trained, then as an Assistant Professor at Harvard, and now as Associate Professor and Director of the NIH-funded Vascular Medicine Program at Stanford. The endothelial lining of blood vessels is only one cell layer thick, but it exerts tremendous control over vessel tone, by producing Nitric Oxide(NO), prostacyclin, and other vasodilators. An endothelial enzyme known as NO synthase, produces NO and citrulline from the amino acid L-arginine. In patients with atherosclerosis, or with risk factors for atherosclerosis, the production of NO is reduced. Vasodilation is impaired in these individuals, and this impairment of endothelial function contributes to reduced coronary and peripheral blood flow. My group was the first to show that the impairment of NO synthesis could be reversed simply by administering exogenous L-arginine. Since then a number of groups including our own, have shown that high doses of arginine(6-9 grams daily) can improve coronary and peripheral blood flow, improve exercise tolerance and relieve symptoms of angina and intermittent claudication. However, it is difficult for patients to take 12-18 capsules of L-arginine daily, which is why I developed the arginine-enriched HeartBar®

The HeartBar® has now been tested in rigorous, double-blind, placebo-controlled trials and has been shown to improve exercise tolerance and reduce pain in patients with coronary and peripheral arterial disease. Although these clinical trials are very gratifying, what I find even more satisfying are the positive results that I have observed in my own clinic. Here are a few representative anecdotes:

A 65 y/o male with chest pain

Mr. M. is the chief executive officer of an educational company. His job is stressful, and his hypertension, hypercholesterolemia, and diabetes have, over the years, taken a toll on his heart. In 1975 he underwent coronary artery bypass grafting X3 (at that time he stopped smoking). Since then he has had two myocardial infarctions and multiple angioplasties. He presented to my clinic in 1995, with an exacerbation of his angina. I increased his medical therapy, getting his blood pressure, diabetes and high cholesterol under control. However, despite the best medical therapy he showed up in my clinic again in 1998 with more chest pain. Coronary angiography at that time showed that his bypass grafts were diffusely diseased, and the severity of disease in his native vessels would make revascularization difficult. He was already on maximal medical therapy, and he was taking nitroglycerin about 3-6 times daily for breakthrough chest pain. I told Mr. M. that he would need to make some lifestyle changes (exercise, stress reduction, diet) to enhance his heart (and endothelial) health. I also asked him to try the HeartBar.

At his next visit to me a couple of weeks later, Mr. M. was radiant. The angina had improved markedly. He rarely needed to use nitroglycerin. He was even able to get back to his old work schedule. At the time of this writing, Mr. M. is enjoying life with less pain.

A 78 y/o male with intermittent claudication

L. M. is a vigorous 78 year old man who looks younger than his stated age. As an alpine biologist, one of his classes each year involved a month of hiking over the heights of Yosemite and King's Canyon. Now, in retirement he is still an outdoorsman, and enjoys outdoor activities with his son. For the last few years though, he had noticed cramping in his legs after walking up a hill. The discomfort would subside if he stood still for a moment, and then he could go on. But about two years ago, the cramping became a real disability for him. He was tightening up after walking a half-mile, and he could only go that far if he walked slowly. The great outdoors was getting farther away for LM.

He came to my Vascular Medicine clinic at Stanford in the spring of 1999. I prescribed Trental 400 tid. He returned to me 6 weeks later with little improvement. At that point I stopped the Trental

and introduced him to the HeartBar. LM began taking two bars daily. It wasn't long before he noticed an improvement, and over time, he continued to improve. At the time of this writing, LM is able to walk faster, without pain, and considers himself unlimited. He is even able to jog a quarter of a mile before he needs to slow down. He's back to the hills, and enjoying the outdoors again with his son.

I hope that you found these anecdotes interesting. I welcome you to send in your own anecdotes regarding your experience with this nutritional therapy.

With warmest regards,
John P. Cooke, MD Ph.D.
Associate Professor and Director
Section of Vascular Medicine
Stanford University School of Medicine

If you have any questions, please feel free to [contact us](#).

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Doctor's Corner

Alan S. Bailor
Cardiovascular Diseases
1330 Cottman Ave.
Philadelphia, PA 19111

Patient Success Story

My 77 year old father had a triple coronary artery bypass grafting procedure in 1984. He was angina free for approximately 10 years. Gradually, since that time, he has experienced progressive angina with exertion. His medications include Norvasc, Imdur, Atenolol, and sublingual Nitroglycerin.

Understandably, he is not anxious to undergo repeat revascularization. Approximately 18 months ago, I read studies which confirmed that L-Arginine, in the form of the HeartBar, increased the blood flow through the coronary arteries substantially. I suggested that my father try one HeartBar twice daily. After approximately 6 weeks of adding two HeartBars daily to his regimen, he is rarely experiencing angina and has none at rest presently.

I am convinced that, without the HeartBars, my father would have had to undergo another revascularization. Thank you, Cooke Pharma, for this wonderful product.

If you have any questions, please feel free to contact us.

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Marcus S. Kryger
Box 280
Forsyth, MO 65653

PVD Patient Success Stories

- 82 Year old white female with ischemic cardiomyopathy and severe peripheral vascular disease by IMEX scan. Unable to walk 1 block due to leg pain and dyspnea. She was scheduled for femoral artery bypass, but started on HeartBar. Three months later, without surgery or other medical changes, she was walking 2 miles daily and continues to do so, without symptoms, 15 months later.
- 50 Year old male with persistent polymorphic ventricular ectopy and paroxysmal dyspnea, 4 months after PTCA/stent placement (with good angiographic results). Two weeks after starting HeartBar, all symptoms resolved, and remains asymptomatic and fully functional 18 months later on 1 HeartBar daily.
- 86 Year old white male with CHF due to ischemic cardiomyopathy and severe leg pain on walking over 50 feet. Started on HeartBar BID, no other changes in medical regime. A month later he repaired his roof by himself without any symptoms. He felt well for 4 months then stopped HeartBar. He rapidly became more dyspneic; restarted HeartBar BID with prompt improvement and went deer hunting this past fall.

If you have any questions, please feel free to [contact us](#).

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Doctor's Corner

Peter Gray
90 South St.
Glens Falls, NY 12801

Great Results--Reducing Angina Episodes, Claudication, Improving Exercise Capacity

Great results regarding:

- Improving exercise capacity in patients with stable angina,
- Reducing anginal episodes, and
- Reducing claudication.

I'm now using it with my father for claudication with excellent results.

If you have any questions, please feel free to [contact us](#).

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Frequently Asked Questions for Patients

Don't see an answer to your question, please [contact us](#).

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What is HeartBar®?

See [What is HeartBar®?](#)

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Who are HeartBar® products for?

HeartBar® products are designed for different individuals:

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HeartBar® Plus, the medical food, is intended for cardiovascular patients who are under the active care of a physician. It is a safe, effective and convenient way that may significantly increase nitric oxide production for an estimated 16 million people who have been diagnosed with coronary and peripheral artery disease. Extensive scientific research shows that nitric oxide is deficient in people with these diseases as well as those with risk factors for heart disease such as high cholesterol, high blood pressure, diabetes, estrogen deficiency, and tobacco use.

HeartBar® Sport, the dietary supplement, is intended for older adults or at-risk individuals who wish to maintain good cardiovascular health, as well as benefit from increased energy and endurance.

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What's in HeartBar®?

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What is L-arginine?

See [L-arginine](#).

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How does HeartBar® Work?

The active ingredient of all HeartBar® products is L-arginine, an amino acid used by the human body to

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Mary R. Gompf from OH

"It was just like my Doctor said. After only 2 weeks of taking the HeartBar, I noticed a dramatic reduction in my angina pain and leg pain. My energy level also increased, allowing me to do more things with my great-grand children that I previously lacked the energy to do. Thank you."

Ms. Jean Lariscy from GA

"I have had so many tests done by the hospital for the burning and pain in my feet and legs. I have taken so many different kinds of medication and nothing has helped. My Cardiologist found I had mild atherosclerosis and believed the HeartBar would help. Within 2 weeks I noticed an improvement. My circulation has improved, my energy has increased, and the burning in my legs and feet and hip is so much better. Thanks to HeartBars. I have told my friends about the HeartBar and suggested they talk to their cardiologist."

Ms. Jeree Perry from KY

"I have lots of 'Natural Energy'. Instead of 52 years of age. I feel 32. I walk 3 to 5 miles a day after working 8 to 10 hours. It can be a 'Life Change'. Thanks."

Bernadette Reid from NY

"I don't expect a cure, but it is just so good not to have that leg pain any more. I can walk so much further."

Mr. Barry Dangler from FL

"My Cardiologist recommended the HeartBar to me. After about 2 weeks, people at work were asking me, 'Barry, what's going on?' I told them about the HeartBar and how much more energy I now have. I was very tired and sleeping a lot. Now I'm back now doing things, like yard work, that I haven't done in 2 years. My Cardiologist has taken me off of Indur for my angina pain now that I'm taking the HeartBar. I feel great."

Ms. Betty Burke from CA

"I had severe burning pain in my left leg when I ran up hills. My AB Index, done by Stanford Research, in my left leg was only .5. I read on the Internet that a .4 Index might require amputation."

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After 2 weeks taking the HeartBar, the burning pain is gone! I can run with no pain. I also don't have any leg pain when playing tennis. I was seen by a vascular surgeon who proclaimed that I had excellent circulation in both legs. HeartBar has really changed my life!"

William E. Doxon from KS

"My name is William E. Doxon. I would like to give you a short overview of my heart and subsequent diabetes history and my experience with HeartBar. I had open-heart surgery in November of 1976. Since then I have had 3 ballooning; I had a light heart attack during the last ballooning. The doctors told me I probably would have a major attack at some point. One month later I did. After taking various heart medications for years, I developed diabetes. My legs and feet have been icy cold for some time. My hips and legs hurt whether working or at rest. In my work, I unload freight loads of chemicals used in commercial dishwashers. I also service the machines.

In July of 1999 my doctor couldn't find a pulse in either foot. I went to a vascular specialist who put in 2 stents, one in each groin area. Still no pulse! In December of 1999 I went back to the same specialist who then put three more stents in the same area. Still no pulse in my feet!!

About two weeks after the last stents, my doctor called and asked me to try a new product called HeartBar. I was to eat two a day. I used them as my midmorning and midafternoon snacks. Within two weeks, I had a weak pulse in both feet. Since then, the pulse has gotten stronger. In fact, I've had to take my shoes off sometimes because my feet were so warm. I can now work or walk without pain. I firmly believe that anyone with vascular problems will benefit from eating two HeartBars a day. I get tired of having to remember to eat anything twice a day. But this is, after all, a medication and should be treated as such. Thanks Cooke Pharam!!!."

Ms. Dorothy Johnston from CA

"Before taking the HeartBar, I had to stop half way up the 15 stairs to my house. I also had to stop part way up an incline to the building where I did my pool therapy because of my angina pain. Now I can walk the stairs and to the pool without stopping and with no pain. I'm also walking 20 minutes to half an hour with a friend at least once a week with no problem. HeartBar has

EX-17
11 0 17

Unither Pharma - Customer's Testimonials

"really made a big difference in my daily life."

Mr. Sam Roska from CA

"I have atherosclerosis in both legs. After 2 angioplasties on my legs, my doctor put me on HeartBar. Further angioplasty presented a 20% risk of amputation. I had been able to walk only up to about 3 minutes before debilitating leg pain forced me to stop. After about a month on the HeartBar, I was able to walk 10 minutes with no pain! I now have much less pain than before."

Charles Schiele from CA

"At a friend's recommendation, I started on the HeartBar about 6 weeks ago. My energy level has really increased. I've more than tripled the number of laps I swim to 20 now, and can swim these faster than before, even the last lap. When I'm done, I feel great; my stamina has so greatly improved. Additionally, my blood pressure has dropped and my appetite for healthy foods has increased. I've also started lifting weights with all this new energy. I feel like a kid again."

Thomas Overbeek from MI

"I have had leg pains for about 10 years. The pain in my left leg became especially bad in the last 6 months. I could barely walk from the bedroom to the bathroom. I couldn't stand up without pain. Because of my worsening condition, I was scheduled for bypass surgery in my leg. My doctor told me my pain would remain, however. But, after 2 weeks taking the HeartBar, the pain in my leg disappeared. It was unbelievable! As scheduled, I went into see my surgeon the day before my surgery; he cancelled the surgery. I haven't felt this good in 10 years. I can walk and climb stairs with no pain now, and can stand for half an hour. My energy level is also up and I can't wait to get out to do things. HeartBar has given me back my life!"

Al White from MI

"I am almost an Octogenarian (in 6 months). My angina pains have left me and my breathing has become a lot easier. I have not had to use my Nitro-Stat pills since I started using HeartBars—not a single one. I got my Doctor's OK first to use the HeartBars."

Mary Sutton from PA

EX. C. P. 18
EX. F. P. 18



Home | [Peer Counselor Login](#) | Peer-to-Peer Marketing | Peer Counselor Application
Request HeartBar® Samples | Order HeartBar® Products | Find a Peer Counselor

Product Information

- ◆ About HeartBar®
- ◆ Product Line
- ◆ Patients FAQs
- ◆ Doctors FAQs
- ◆ Common Terms

Company Information

- ◆ Contact Information
- ◆ News
- ◆ Background

Science Library

- ◆ Reviews
- ◆ Medical Abstracts
- ◆ Clinical Studies
- ◆ Pre-Clinical Studies
- ◆ About Heart Disease

Scientific Advisory

Patients' Testimonials

Doctor's Corner



A Unither Pharmaceuticals Company

About HeartBars

If you have heart disease, take two **HeartBars** a day to feel a difference within two weeks!

Recommended by doctors for daily use
Based on Nobel Prize medical science and clinical research

Eating two **HeartBars** a day helps open blood vessels and improves circulation with the following results:

- Reduces painful symptoms of heart disease such as angina and leg pain
- Helps increase mobility
- Helps improve ability to exercise without pain, discomfort, or fatigue
- Increases energy levels to help you live a more active and enjoyable life

Results are usually experienced within the first two weeks. After two weeks, one **HeartBar®** a day may be sufficient to maintain results.

HeartBar® was developed following ten years of extensive research at Stanford University and other leading medical centers.

Based on the science that won the 1998 Nobel Prize in medicine, **HeartBars** feature a patented formula containing L-arginine, which helps improve circulation and create smoother, more efficient blood flow.

Ask your doctor or medical professional about **HeartBars**, and learn how it helps people with heart disease to live a more active and enjoyable life.

If you have any questions, please feel free to contact us.

All Rights Reserved, Cooke Pharma 2001

The price for 32 servings any combination of HeartBar® products is as follows:

- \$59.99 for a single 32-serving order, plus shipping & handling
- \$49.99 for a 32-serving subscription order, plus shipping & handling

[\[back to top\]](#)

How many HeartBars should a consumer eat a day to receive all of the heart and vascular benefits?

Clinical research shows that, for best results, significant improvement in blood circulation, significant improvement (66%) in pain free walking distance and reduction in total and LDL cholesterol by 10%-15%, are achieved by eating two bars a day.

Check out the [HeartBar® product line](#) for the new and exciting flavors!

[\[back to top\]](#)

Who regulates medical foods?

The U.S. Food and Drug Administration regulates medical foods. By law, medical foods are products specially formulated to supplement oral intake as part of the diet in the overall medical management of a condition or disease for which distinct nutritional requirements are established by medical evaluation. Medical foods are only for use under the supervision of a physician. HeartBar® meets the requirements of a medical food.

[\[back to top\]](#)

What are other examples of medical foods?

HeartBar® meets the requirements of a medical food product. According to the FDA, other examples of medical foods include products for kidney and liver disease, compromised immune functions, diabetes, burns, Crohn's Disease and short bowel syndrome. They are not intended for use like conventional food.

[\[back to top\]](#)

When was Cooke Pharma established?

The Only Medical Food for the Dietary Management of Vascular Disease

HeartBar[®]

Use under the supervision of a physician.

Ask your pharmacist.

Recommended by Doctors for Daily Use

- *Improves Circulation*
- *Helps Reduce Angina & Leg Pain*
- *Provides Increased Energy*

16 50g (1.76 OZ) HeartBars
NET WT. 800g (28.2 OZ [1 LB 12.2 OZ])

Ex. F. p. 1

**If you have heart disease, take two HeartBars
a day to feel a difference within two weeks.**

Eating two HeartBars a day helps open blood vessels
and improves circulation with the following results:

- Reduces painful symptoms of heart disease
such as angina and leg pain
 - Helps increase mobility
- Helps improve ability to exercise without pain,
discomfort, or fatigue
- Increases energy levels to help you live a
more active and enjoyable life

Results are usually experienced within the first two weeks.
After two weeks, one HeartBar® a day may be sufficient to maintain results.

Use under the supervision of a physician. Ask your pharmacist.



Distributed by Cooke Pharma Inc., Belmont CA 94002
For more information about HeartBar®,
call us toll free at (888) 808-6838
or visit our web site at www.cookepharma.com

1700 3200
2/1/02

Dietary Supplement for Heart Health, Energy and Vitality

Cranberry
 Flavored

HeartBar®

Sport

Dietary Supplement

3g L-Arginine per Serving

Clinically Proven Results

*Improves endurance, circulation and energy**

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

8 BARS | NET WT 9.87 OZ (280g)

5/16/2002

The Heart of the Classics

The Finest Classical Music...A Gift to You From HeartBar®

[Redacted]

[Redacted]

HeartBar
HeartBar
HeartBar

Is HeartBar® Right For You?

Anyone concerned about the health of their heart will appreciate the benefits of adding HeartBar to his or her diet. Because HeartBar is high in protein, vitamins, and minerals, and also low in fat and calories, it is an ideal snack food or meal replacement for those who are on the go or are watching their weight.

If you are elderly, you might want to consider that as we age, our need for arginine in the diet increases. Eaten in the right amount, arginine can help prevent a variety of age-related vascular problems, including "hardening of the arteries" and plaque formation, and prevent or reverse the symptoms associated with them. If you have any of the following risk factors or symptoms of heart disease, HeartBar may be an important part of your daily health program:

Risk Factors

- ♥ High Cholesterol
- ♥ High Blood Pressure
- ♥ Obesity
- ♥ Diabetes
- ♥ Low Estrogen
- ♥ Smoker
- ♥ Family History

Symptoms

- ♥ Chest pains
- ♥ Leg Pains
- ♥ Winded When Climbing Stairs
- ♥ Low Energy



is the smart choice

Call HeartBar® Toll Free 1 888 808 6838

HeartBar® Improves Your Blood Flow.

Because the key ingredient in HeartBar® improves the elasticity of your blood vessels and helps to keep vessels open, eating HeartBar® products can contribute to better blood flow throughout your body and can improve your aerobic performance. For these reasons, even those who are not experiencing heart disease or age-related symptoms choose to make HeartBar® a part of their daily regimen.

Clinical Research Confirms that HeartBar®...

- ♥ Improves circulation and blood flow for better heart health.
- ♥ Increases exercise ability and improves energy levels.
- ♥ Relieves painful symptoms such as angina and leg pain.
- ♥ Has been proven safe and effective.

If you are...

- ♥ Athletic
- ♥ Under Stress
- ♥ Dieting
- ♥ Elderly

**YOU WOULD NEED TO TAKE UP TO 12 LARGE,
ARGININE PILLS PER DAY TO EQUAL THE
AMOUNT OF ARGININE IN JUST 2 HEARTBARS®.**



is the smart choice

Call HeartBar® Toll Free 1 888 808 6838

See Results in Two Weeks!

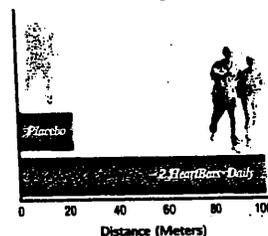
In clinical studies, after only two weeks of eating two HeartBars® daily, patients showed significant improvement in angina scores and quality of life.¹ In patients suffering from PAD (peripheral artery disease), HeartBar® was shown to significantly improve the ability to walk pain free.² After the initial two weeks, one HeartBar® a day may be sufficient to maintain these results.

- ♥ 150% improvement in coronary blood flow response
- ♥ 70% reduction in angina pain
- ♥ 66% increase in ability to exercise

**For More Information,
Or To Order HeartBar®,
Call Us Today!**

*Free Sample Kit Available.
Ask Us About Our Special Discount Program.*

Change in Pain-Free
Walking Distance



1. Maxwell AJ, Zapein MP, Cooke JP. Endothelial dysfunction in hypercholesterolemia is reversed by a nutritional product designed to enhance nitric oxide activity. *Circulation Drug Ther.* 2000;6(1):58.
2. Data available. Cooke Pharma, Inc.

Try HeartBar® Today... It really works!

"I couldn't even walk a hole on the golf course without a golf cart. And, I couldn't walk over a quarter mile without pain in my legs. Now I have no pain." — Gary Martinelli, California

Call HeartBar® Toll Free 1 888 808 6838



2001 United Therapeutics Corporation Annual Report

**Medicines
for Life[®]**

Arginine Is Patented for the Treatment of Cardiovascular Disease

Arginine is a natural amino acid that is essential for the production of nitric oxide, a powerful vasodilator. It is also a key component of the body's natural defense system against cardiovascular disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.



"In my experience, recommending Heart Bar has helped to stop heart disease in my patients."

Joe Prendergast, M.D.
Diabetes Specialist

Almost every doctor who has treated patients with heart disease has experienced the consequences of high cholesterol, high blood pressure, and high triglyceride levels. While medications can help control these conditions, they do not always work. Arginine is a natural defense system against cardiovascular disease. It is also a key component of the body's natural defense system against cardiovascular disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.

In earlier centuries, when average life expectancy was around 40 years, the risk of cardiovascular disease was the highest concern. In those days, infectious diseases took most people's lives. In the 19th century, when life expectancy increased to around 50 years, infectious diseases were still a major concern. In the 20th century, when life expectancy increased to around 70 years, cardiovascular disease became the leading cause of death. This is because of the increase in the number of people who are living longer and the increase in the number of people who are living longer with cardiovascular disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.

High blood pressure is a major risk factor for cardiovascular disease. It is caused by a narrowing of the blood vessels, which forces the heart to pump harder to get blood through. This can lead to atherosclerosis, which is the buildup of plaque in the arteries. This can lead to heart disease and stroke. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.

Recent studies show that people with high levels of another molecule called asymmetric dimethylarginine (ADMA) are at a higher risk of heart disease. ADMA is actually produced by the body in response to stress, and it is a major risk factor for heart disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.

As most people age, their blood pressure rises, and this is a major risk factor for heart disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.

In the early 1990s, when the average life expectancy was around 70 years, the risk of cardiovascular disease was the highest concern. In those days, infectious diseases took most people's lives. In the 20th century, when life expectancy increased to around 70 years, infectious diseases were still a major concern. In the 21st century, when life expectancy increased to around 80 years, cardiovascular disease became the leading cause of death. This is because of the increase in the number of people who are living longer and the increase in the number of people who are living longer with cardiovascular disease. The discovery of this natural defense system was made by Dr. James O'Keefe, M.D., Professor of Medicine at Saint Louis University School of Medicine, who has now patented the use of arginine for the treatment of cardiovascular disease.



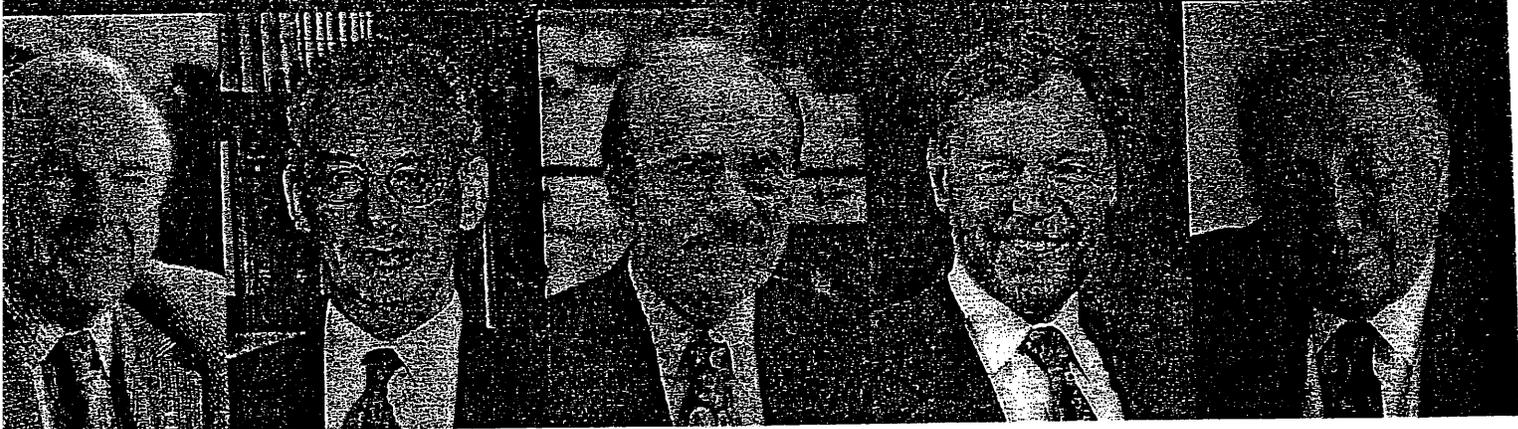
DRUG DEVELOPMENT IS WAR
ANNUAL REPORT 2000



 **United
Therapeutics**
CORPORATION
Medicines for Life™

ENT 01

SCIENTIFIC ADVISORY BOARD



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1976 Nobel Laureate in Physiology or Medicine
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1982 Nobel Laureate in Physiology or Medicine
Chairman of the Scientific Advisory Board



United Therapeutics benefits from having an advisory board that comprises a renowned group of experts. Chaired by the discoverers of the prostacyclin molecule, our Scientific Advisory Board includes three Nobel Laureates: Sir John Vane, D.Sc., F.R.S., co-discoverer of prostacyclin; Professor Baruch S. Blumberg, Ph.D., discoverer of the hepatitis B virus marker; and Professor Louis J. Ignarro, Ph.D., co-discoverer of nitric oxide's role in the cardiovascular system. Our Scientific Advisory Board provides valuable vision, product guidance, and industry contacts. The Board's medical acumen is provided by thought-leaders Robyn J. Barst, M.D., Professor of Pediatrics, Columbia University College of Physicians and Surgeons, Director, Pulmonary Hypertension Center, New York Presbyterian Hospital; Professor John Eric Deanfield, M.B., BChir, F.R.C.P., Senior Lecturer at St. Bartholomew's Hospital, London; Professor Raymond A. Dwek, F.R.S., Director, University of Oxford Glycobiology Institute, Chairman of the Department of Biochemistry; Professor Victor J. Dzau, M.D., Chairman of the Department of Medicine of Brigham & Women's Hospital, Harvard Medical School; Professor Salvador Moncada, M.D., Ph.D., D.Sc., co-discoverer of prostacyclin and Vice Chairman of the Scientific Advisory Board; Urban Ramstedt, Ph.D., Virus Research Institute in Cambridge, Massachusetts; Lewis Rubin, M.D., Director, Pulmonary/Critical Care Division, University of California, San Diego; and Professor Sir Magdi Yacoub, M.D., F.A.C.S., England's National Heart and Lung Institute.

HEARTBAR

HeartBar is the only medical food for the dietary management of vascular disease. Clinical studies conducted by Cooke Pharma have demonstrated the ability of the HeartBar to reduce painful symptoms associated with cardiovascular diseases, as well as to increase a patient's exercise capacity and to improve quality of life scores. Cooke Pharma owns the sole patent rights to use the HeartBar's key ingredient, arginine, for cardiovascular diseases. In 1998, three American scientists received the Nobel Prize for their discovery that healthy blood vessels produce nitric oxide, which keeps blood vessels relaxed and open. The HeartBar increases the vaso-relaxing effect of nitric oxide. Randomized, double-blinded clinical

studies published in medical journals and presented at the 2000 American Heart Association meeting have shown that the HeartBar works. This year our subsidiary, Unither Pharmaceuticals, will test the ability of the HeartBar to relieve angina in a large, multi-center, well-controlled study. The HeartBar is included in the Physician's Desk Reference.



For Immediate Release
For Further Information Contact:
Therese Fergo 301-608-9292
Email Therese@unither.com

**UNITED THERAPEUTICS ACQUIRING COOKE PHARMA,
EXPANDING INTO ANGINA AND CORONARY ARTERY DISEASE**

Silver Spring, MD and Belmont, CA, December 18, 2000 – United Therapeutics Corporation (NASDAQ: UTHR) announced today that its wholly owned subsidiary, Unither Pharmaceuticals, Inc., is acquiring all of the assets of Cooke Pharma, Inc., the exclusive maker of the HeartBar®, the first and only medical food for angina and other cardiovascular conditions. Medical foods are regulated by the FDA.

The HeartBar relieves the symptoms of heart disease by increasing the diameter of blood vessels and thereby increasing blood flow. Clinical studies conducted by Cooke Pharma have demonstrated convincingly the ability of the HeartBar to reduce painful symptoms of cardiovascular disease, increase exercise tolerance and improve the quality of life. Privately held Cooke Pharma is the only company that owns the patent rights to use the HeartBar's key ingredient, arginine, in a food product for cardiovascular diseases. Cooke Pharma sold over four million HeartBars as an over-the-counter product during 1999-2000.

The HeartBar, which is included in the Physicians Desk Reference, increases the relaxing effect of nitric oxide produced by blood vessels. In 1998, three American scientists received the Nobel Prize for their discovery that healthy blood vessels make nitric oxide, which keeps them relaxed and open. Randomized, double-blinded clinical studies published in leading medical journals and presented at the 2000 American Heart Association conference have shown that the HeartBar reduces angina and significantly improves exercise ability as compared to placebo. Cooke Pharma has other products in development based on its issued and pending patents targeting those at risk of heart disease and for overall cardiovascular health.

The Cooke Pharma Scientific Advisory Board includes two Nobel Laureates in Medicine, Sir John Vane and Dr. Louis Ignarro, as well as the Chairman of Medicine of Harvard Medical School, Dr. Victor J. Dzau, among other experts in cardiology. The founder of Cooke Pharma, Dr. John Cooke, is the Director of Vascular Medicine at the Falk Center for Cardiovascular Research at Stanford University.

"With the acquisition of Cooke Pharma's impressive technology platform, United Therapeutics gains a pioneering medical food product with dynamic growth potential in the \$13 billion heart disease market, as well as the larger market of 60 million Americans who are at risk of developing heart disease," said Dr. Barry Kanarek, President and COO of Unither Pharmaceuticals. "Cooke Pharma complements United Therapeutics' mission

to develop highly effective, clinically proven therapies to combat cardiovascular disease," Dr. Kanarek said.

The acquisition is structured as a taxable stock-for-assets purchase with a residual royalty stream. United Therapeutics will issue approximately 300,000 shares of its common stock to Cooke Pharma, subject to adjustment within a year, and Unither Pharmaceuticals agreed to pay a single-digit cash royalty to Cooke Pharma on sales of Cooke Pharma products up to an additional \$49 million, subject to possible reduction. Unither Pharmaceuticals will create a new wholly owned subsidiary which will operate under the Cooke Pharma name and will be managed by Cooke Pharma's existing management team. Closing of the asset purchase agreement is contingent upon several consents and approvals, including approval of the transaction by Cooke Pharma's shareholders by December 31, 2000.

"This transaction will create a winning combination that can benefit millions of consumers and patients who have or are at risk of developing heart and vessel disease," said John Cooke. "Both United Therapeutics and Cooke Pharma share a strong commitment to improving cardiovascular health and saving lives. We believe United Therapeutics has the vision, clinical expertise and resources to make the HeartBar and future formulations market leaders worldwide," continued Dr. Cooke.

Dr. Kanarek added, "Led by Dr. Cooke, Cooke Pharma has a respected record of combining medical science with product innovation. We expect the HeartBar could become an important weapon against heart disease."

Through his own extensive research at Stanford University, Dr. Cooke pioneered the use of arginine and other nutrients to improve vessel function and relieve symptoms in patients with peripheral vascular disease and with coronary artery disease. Dr. Cooke formulated these nutrients into medical foods and founded Cooke Pharma in 1995 to produce and market the products. The HeartBar is available over-the-counter at pharmacies nationwide. Cooke Pharma has plans to launch a second product, a drink, in 2001.

United Therapeutics is a biotechnology company focused on combating cardiovascular, inflammatory and infectious diseases with unique therapeutic products.

* * *

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Unither Pharma, Inc. ("Unither Pharma") is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. Unither Pharma is a wholly owned subsidiary of Unither Pharmaceuticals,

Decision and Order

Inc., which is wholly owned by respondent United Therapeutics Corporation.

2. Respondent United Therapeutics Corporation (“United Therapeutics”) is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. Unless otherwise specified, “respondents” shall mean United Therapeutics Corporation, Unither Pharma, Inc., and their successors, assigns, officers, agents, representatives and/or employees.
3. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
4. “Food” and “drug” shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and “over-the-counter” shall mean available without a prescription.

Decision and Order

5. “L-Arginine product” means any food, over-the-counter drug, medical food, or dietary supplement which contains as an ingredient the amino acid L-arginine.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of HeartBar, HeartBar Plus, HeartBar Sport (collectively “HeartBar”), or any other L-Arginine product used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such product:

- A. substantially decreases leg pain for people with cardiovascular disease;
- B. reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk;
- C. prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, or reduces the risk of developing cardiovascular disease;
- D. reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or
- E. improves endurance, circulation, and energy for the general population;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Decision and Order

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not make any representation, in any manner, expressly or by implication, about the health benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Decision and Order

V.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

IT IS FURTHER ORDERED that respondents shall, within thirty (30) days after the date of service of this order, send by first class certified mail, return receipt requested, to each distributor, seller, or purchaser for resale of any HeartBar product with whom respondents, or their agents, successors, or assigns, have done business since January 1, 2001, notice of this order in the form attached as Attachment A. The mailing shall not include any other documents.

In the event that respondents receive any information that, subsequent to its receipt of notice of this order, any distributor, seller, or purchaser for resale is using or disseminating any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order, respondents shall: (1) immediately send such distributor, seller, or purchaser for resale a letter requesting that it stop using or disseminating any such advertisement or promotional material and notifying it that any such use or dissemination will be reported to the Commission; and (2) within thirty (30) days notify the Associate Director for Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, in writing, of the identity of such distributor, seller, or purchaser for resale and its use or dissemination of any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order.

Decision and Order

VII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation including videotape recordings of all such broadcast advertisements;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall deliver a copy of this order to all current and future officers, directors, and managers, and to all current and future employees, and agents having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and, for a period of five (5) years after the date of service of this order, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

Decision and Order

IX.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XI.

IT IS FURTHER ORDERED that this order will terminate on July 22, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes

Decision and Order

later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Decision and Order

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED
[To be printed on letterhead of Unither Pharma, Inc. or
United Therapeutics Corporation]

[date]

Dear [distributor, seller, or purchaser for resale]:

We write to announce Unither Pharma's new advertising policy for HeartBar related products. As you may be aware, on _____, 2003, the Federal Trade Commission ("FTC") announced a settlement and consent agreement with Unither Pharma, Inc. and United Therapeutics Corporation related to the marketing of HeartBar products. This agreement requires that the claims we make when marketing HeartBar products must be accurate and grounded in competent and reliable scientific evidence.

We are committed to obeying fully the requirements of this settlement agreement with the FTC, while, at the same time, vigorously supporting sales of HeartBar products. To better explain how this advertising policy change may affect you, we briefly summarize the agreement with the FTC and ask for your full cooperation in ensuring that HeartBar products are sold in a manner consistent with this policy.

The Settlement Agreement

In its complaint accompanying the consent order, the FTC alleged, among other things, that our advertisements made unsubstantiated claims that: (1) HeartBar substantially decreases leg pain for people with cardiovascular disease; (2) HeartBar reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) HeartBar prevents age-related vascular problems, including "hardening of the

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arteries” and plaque formation, and reduces the risk of developing cardiovascular disease; (4) HeartBar reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, and medications, such as nitroglycerin, in patients with cardiovascular disease; and (5) HeartBar Sport improves endurance and energy for the general population.

The FTC’s complaint further alleged that our advertisements falsely claimed that clinical studies, research, and/or trials show that: (1) HeartBar decreases angina pain, including by as much as 70% within two weeks; (2) HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; and (4) HeartBar Sport improves endurance and energy for the general population.

We deny the FTC’s complaint allegations and do not admit to any wrongdoing or violation of law. However, in order to resolve this matter, Unither Pharma, Inc. and United Therapeutics Corporation have entered into a settlement agreement with the FTC. Pursuant to the consent agreement, Unither Pharma, Inc. and United Therapeutics Corporation are required to request that our distributors and sellers stop using or distributing advertisements, packaging, or promotional materials containing claims challenged by the FTC. We are sending you this letter, because you are one of our distributors, sellers, or purchasers for resale.

Unless we have competent and reliable scientific evidence to support our claims, the consent agreement prohibits us from representing that any HeartBar product:

- substantially decreases leg pain for people with cardiovascular disease;
- reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any

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other medical condition or health risk;

- prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, or reduces the risk of developing cardiovascular disease;
- reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or
- improves endurance, circulation, and energy for the general population.

The consent agreement also prohibits us from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research regarding any HeartBar product.

Our Commitment

Unither Pharma, Inc. and United Therapeutics Corporation are committed to the continued study of the health benefits of the HeartBar product and L-arginine through scientifically valid, well-controlled clinical testing. It is the companies’ hope that such testing will produce competent and reliable scientific evidence necessary to support additional claims that supplemental L-arginine provides certain health benefits. However, Unither Pharma, Inc. and United Therapeutics Corporation wish to emphasize that it is critically important that claims made pertaining to such health benefits only be made based upon such competent and reliable scientific evidence.

Your Assistance

We request your assistance in complying with the consent agreement. Please discontinue using, distributing, or relying on any of our advertising or promotional material, including

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packaging, for any HeartBar product that makes any of the claims mentioned above. Please also notify any of your customers who resell these products and who may have such materials to discontinue using such promotional materials. If we receive information that you are continuing to use materials that do not comply with the consent agreement, we will notify the FTC of your failure to comply with this request.

We very much look forward to our mutual continued success and thank you very much for your assistance.

Sincerely,
[name]

President
Unither Pharma, Inc./United Therapeutics
Corporation

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Unither Pharma, Inc. and its parent company, United Therapeutics Corporation (collectively “Unither”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves allegedly misleading representations about Unither’s HeartBar products, chewy food bars and powders enriched with L-Arginine, vitamins, and minerals. HeartBar’s labeling describes the product as the only “medical food” for the dietary management of heart and vascular disease.

According to the FTC complaint, Unither failed to have substantiation for the claims that HeartBar: (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, and reduces the risk of developing cardiovascular disease; (4) reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, and medications, such as nitroglycerin, in patients with cardiovascular disease; and (5) improves endurance and energy for the general population. Among other reasons, several of the representations are not supported by any clinical studies on humans. Other representations are based on results reported in studies that suffer from various flaws, including the failure to account for the placebo effect and extremely small sample sizes, such that the

Analysis

experience of a single or a few subjects account for the benefits purportedly experienced by the active group as a whole.

The complaint further alleges that, contrary to Unither's claims, clinical studies, research, and/or trials do not show that HeartBar: (1) decreases angina pain, including by as much as 70% within two weeks; (2) decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; or (4) improves endurance and energy for the general population.

The proposed consent order contains provisions designed to prevent the Unither from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that HeartBar (HeartBar, HeartBar Plus, or HeartBar Sport), or any other L-Arginine product used in or marketed for the treatment, cure, or prevention of cardiovascular disease, or the improvement of cardiovascular or vascular function: (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk; (3) prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, or reduces the risk of developing cardiovascular disease; (4) reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or (5) improves endurance, circulation, and energy for the general population, unless the claims are substantiated by competent and reliable scientific evidence.

Part II of the order requires that Unither possess competent and reliable scientific evidence to support any future claims about the health benefits, performance, or efficacy of any food, medical food, or dietary supplement used in or marketed for: (1) the

Analysis

treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function. For the same products covered in Part II, Part III of the order prohibits Unither from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Parts IV and V of the order permit drug claims permitted in labeling under any tentative final or final standard promulgated by the FDA, or under any new drug application approved by the FDA, and any representation for any product permitted in labeling by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part VI of the order mandates that the respondents notify their distributors as to the claims the Commission has challenged and report to the Commission any distributors who continue to make claims that the Commission's order prohibits.

Parts VII, VIII, IX, and X of the order require Unither to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

SNORE FORMULA, INC., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4090; File No. 0223247
Complaint, July 24, 2003--Decision, July 24, 2003*

This consent order, among other things, requires Respondent Snore Formula, Inc. – and its officers, Respondents Dennis H. Harris, M.D., Ronald General, and Gerald L. "Jerry" Harris, also doing business as KJ Enterprises – to possess and rely upon competent and reliable scientific evidence to substantiate representations that “Dr. Harris' Original Snore Formula” tablets – or any other food, drug, device, service, or dietary supplement – prevents sleep apnea in adult or child users who would otherwise develop sleep apnea; treats sleep apnea; or eliminates, prevents, or reduces snoring. The order also requires Respondent Harris to possess and rely upon competent and reliable scientific evidence – and an actual exercise of his represented expertise – to substantiate representations he makes as an expert endorser. In addition, the order requires the respondents to affirmatively disclose a warning about sleep apnea and the need for consultation with a physician or a specialist in sleep medicine whenever they represent that a product or service that has not been shown to be effective in the treatment of sleep apnea is effective in eliminating, preventing, or reducing snoring. The order also prohibits the respondents from providing to any person or entity “means and instrumentalities” that contain any claim about the benefits, performance, efficacy, or safety of any food, drug, device, service, or dietary supplement – unless such claim is true and substantiated by competent and reliable scientific evidence – and from making false claims about scientific support for any product or service.

Participants

For the Commission: *Jonathan Cowen, Jock Chung, J. Reilly Dolan, and Elaine D. Kolish.*

For the Respondents: *Claude Wild III and James Prochnow, Patton Boggs LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Snore Formula, Inc., a corporation; Dennis H. Harris, M.D.,

Complaint

individually and as an officer of Snore Formula, Inc.; Ronald E. General, individually and as an officer of Snore Formula, Inc.; and Gerald L. “Jerry” Harris, an individual, also doing business as KJ Enterprises (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Snore Formula, Inc., is an Arizona corporation with its principal office or place of business at 4015 N. 40th Place, Phoenix, AZ 85018.
2. Respondents Dennis H. Harris, M.D., and Ronald E. General are officers of Snore Formula, Inc. Individually or in concert with others, they formulate, direct, or control the policies, acts, or practices of the corporation. Their principal place of business is the same as that of Snore Formula, Inc.
3. Respondent Gerald L. Harris is an individual also doing business as KJ Enterprises. Gerald Harris’ principal office or place of business is 3321 Old Mallard Road, Enid, OK 73703.
4. Individually or in concert with others, respondents Snore Formula, Inc.; Dennis H. Harris, M.D.; and Ronald E. General have formulated, manufactured, labeled, advertised, offered for sale, sold, and distributed products to the public, including Dr. Harris' Original Snore Formula tablets (also called “caplets”). Dr. Harris' Original Snore Formula tablets are "foods" and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
5. Gerald L. Harris is a distributor of Dr. Harris’ Original Snore Formula tablets and is the owner and operator of the <www.snoreformula.com> Website. Individually or in concert with others, he has advertised, offered for sale, sold, and distributed products to the public, including Dr. Harris' Original Snore Formula tablets.
6. The acts and practices of respondents alleged in this complaint

Complaint

have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

7. To induce consumers and distributors to purchase Dr. Harris' Original Snore Formula Tablets, respondents Snore Formula, Inc.; Dennis H. Harris, M.D.; and Ronald E. General have disseminated or have caused to be disseminated promotional materials, including but not necessarily limited to the attached Exhibits A, B, and C. Distributors, including but not necessarily limited to respondent Gerald L. Harris, have further disseminated or caused to be disseminated these promotional materials. These promotional materials contain the following statements:
 - a. Exhibit A – promotional audio cassette (transcript attached as Exhibit A-1): "The True Facts About Snoring' By Dennis H. Harris, MD"

MALE ANNOUNCER: Welcome to this week's edition of Medical Milestones, the show that brings you information vital to your good health. Our guest this week is Dr. Dennis Harris. Dr. Harris is an expert on snoring. He will be sharing some of the latest information on the causes and treatments for snoring. Exh. A-1 at 3.

DR. DENNIS HARRIS: [Twenty-five] percent of all pre-adolescent children in the United States are snorers.

CHRIS McKAY [HOST]: Twenty-five percent?

DR. DENNIS HARRIS: Yeah. And not only that, with kids it's even worse because they develop these huge tonsils and adenoids and they literally block off the airflow, and most of these kids actually have a condition called sleep apnea, which is a much more serious problem, and we'll talk about it in a little more detail as the show goes on. But it is a big problem and it really does need to be taken care of in kids. Exh. A-1 at 11.

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DR. DENNIS HARRIS: Yeah. So, you can see that more people will join that group of chronic snorers as they age and not only that, what those figures don't show is that very definitely the snoring progressively gets worse as time goes on. Exh. A-1 at 14.

DR. DENNIS HARRIS: Now, the incredible part of that is that, at that point, 20 percent of all those people that are chronic snorers will then go on to progress to a very serious problem called sleep apnea. Exh. A-1 at 15.

DR. DENNIS HARRIS: We used to think in medicine that people developed sleep apnea and that was a separate condition. But like I just pointed out, it is not a separate condition. It is the end result of somebody who first begins to snore progressing all the way through these different stages and ending up with sleep apnea. Exh. A-1 at 16.

CHRIS McKAY: Now, Doctor, we've spent some time here talking about the problem. You actually have come up with a solution, is that correct? Exh. A-1 at 16.

DR. DENNIS HARRIS: [W]e've had about 100,000 people that have used the product. I did -- I did a lot of testing for about two years prior to the time that we put it on the market. I tested it on about 220 patients and, you know, we wanted to see how effective it really was.

CHRIS McKAY: Sure. And the results are?

Complaint

DR. DENNIS HARRIS: The results were wonderful. We were hoping that it was maybe going to help 50 percent of the people or so.

CHRIS McKAY: Yeah.

DR. DENNIS HARRIS: In reality, 86 percent of the people that were taking this formula had really good to excellent results.

CHRIS McKAY: Oh, that's fantastic.

DR. DENNIS HARRIS: Yeah. And that's really kind of held up -- we run about 86 to 90 percent of the people that have good results that take it. Exh. A-1 at 20.

CHRIS McKAY: Now, Doctor, will your product help in those instances?

DR. DENNIS HARRIS: What we find is that in the early stages of sleep apnea, we do have a high rate of success. But once it reaches a moderate to severe level, I mean, that really is a structural problem that demands a physical solution to it.

CHRIS McKAY: So, what you're really saying is people have to understand that they need to take care of this early on.

DR. DENNIS HARRIS: That's the good news.

CHRIS McKAY: Okay.

DR. DENNIS HARRIS: That's the good news, exactly. You know, we didn't have good ways to handle snoring for a long period of time, and so, people did go through this progression. But the good news is that you can stop this. You can absolutely stop this progression. Exh. A-1 at 24-25.

DR. DENNIS HARRIS: Anyhow, what are some of the things that really occur? You know, they started gathering more statistics about snoring, and lo and behold, what they started to realize was that there are both short-term and long-term problems, medical problems associated with snoring. For example, the long-term medical problems are a 400 to 500

Complaint

percent increase in the level of risk of developing heart attacks, strokes and high blood pressure compared to non-snorers. Exh. A-1 at 26.

DR. DENNIS HARRIS: [T]he good news is we can stop that whole thing from getting to that point.

CHRIS McKAY: That's great. Dr. Harris, you've convinced me. I'm going to put your product to the test and try it myself. I'd encourage my listeners to do the same. What an easy solution. Exh. A-1 at 28.

DR. DENNIS HARRIS: One real parting thought. If you don't carry anything away, if you hear -- if you're a listener and you haven't carried anything away that we've talked about, remember one thing, we have the opportunity now of stopping this progression of snoring, and when you stop it, at that point, the healing power of your body takes over, and eventually, all of these -- all of this damage repairs itself and you get back to normal.

Don't wait. Pick up the phone today, try our product. It is absolutely without risk to you because we have a 100 percent money back guarantee. You have nothing to lose but your snoring.

CHRIS McKAY: You heard it here, first. Again, I encourage anyone who's experiencing snoring to pick up the phone and call Dr. Harris. Exh. A-1 at 28-9.

b. Exhibit B – Brochure: "Dr. Harris' Original Snore Formula"

Dr. Harris' Original Snore Formula

86% of those using this formulation had good to excellent

Complaint

results

DANGERS OF SNORING:

- Snorers have a markedly higher risk of developing heart attacks, high blood pressure, or strokes.
- Snoring often produces daytime sleepiness or daytime fatigue.
- Snorers have a much higher rate of automobile accidents than non-snorers.
- Snoring causes sleep disturbances that lead to increased anxiety, hyperirritability decreased memory, and poor concentration.

How Dr. Harris' Original Snore Formula™ Works:

The unique combination of natural enzymes metabolizes the secretions, allowing the body to absorb them. The herbs reduce the tissue swelling. The result is to open the airway, smooth out the airflow and eliminate the snoring.

About Dr. Harris' Original Snore Formula™:

This unique formulation was created by Dennis H. Harris, M.D., a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results.

Snoring is a condition that is associated with serious and potentially life-threatening medical problems. Snorers have a much higher risk of heart attacks, high blood pressure, and strokes. Snoring also produces sleep disturbances in the person snoring and their mate.

Complaint

- c. Exhibit C – Brochure: "Dr. Harris' Original SNORE
FORMULA Product Information Booklet"

WHY SHOULD I WORRY ABOUT SNORING?

Although snoring has been the object of jokes and cartoons, medical science has determined that snoring is associated with serious medical conditions. Snorers are known to have a much higher rate of heart attacks, strokes and high blood pressure than non-snorers. The risk of developing these medical problems increases the longer that a person snores and the more severely they snore. Therefore, it is critical that snoring be brought under control and kept under control indefinitely.

CAN I GIVE DR. HARRIS' ORIGINAL SNORE
FORMULA® TO MY CHILD?

Since we no longer remove children's tonsils and adenoids routinely, it is estimated that 20-25% of all children are now chronic snorers. Many of these children also suffer from sleep apnea, a condition in which the person completely stops breathing for up to 30 seconds or more several times each hour. This is a serious medical condition!

Dr. Harris' Original Snore Formula® is being taken by hundreds of children across the country and appears to be quite safe.

HOW EFFECTIVE IS DR. HARRIS' ORIGINAL SNORE
FORMULA®?

Two years of clinical testing by Dennis Harris, MD on 200 chronic snorers produced good to excellent results in 86% of the test subjects taking this formulation.

Complaint

Good Housekeeping, in an independent study, demonstrated that the formulation used in Dr. Harris' Original Snore Formula® produced major improvement in the vast majority of test subjects.

8. Respondent Gerald L. Harris has disseminated additional promotional materials, including but not necessarily limited to the <www.snoreformula.com> Website, attached as Exhibit D, that contain statements based upon the promotional materials described in Paragraph 7. These additional promotional materials contain the following statements:

Exhibit D – Website <www.snoreformula.com>

SNORE FORMULA, INC.

KJ Enterprises

A unique combination of all natural herbs and enzymes that work together to prevent snoring. Statistics have proven that over 40% of the population or 100 million people in the United States are chronic, regular snorers!

DANGERS OF SNORING:

- Snorers have a markedly higher risk of developing heart attacks, high blood pressure, or strokes.
- Snorers have a 300% higher risk of becoming involved in an automobile accident.
- Snorers have a 400% to 500% higher risk of daytime fatigue.
- Snoring causes sleep apnea, a serious medical condition, in 20% of all chronic snorers
- 25% of all preadolescent children are chronic snorers, and most of these have some form of sleep apnea, a serious medical condition.
- Snoring causes sleep disturbances that lead to increased

Complaint

anxiety, hyperirritability, decreased memory and poor concentration.

This unique formulation was created by Dennis H. Harris, MD, a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results.

Good Housekeeping magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users. **Over 150,000 people have used the product over the past 36 months with good results.**

9. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that:
 - a. Dr. Harris' Original Snore Formula tablets prevent sleep apnea in adult and child users of the product who would otherwise develop sleep apnea;
 - b. Dr. Harris' Original Snore Formula tablets treat the "early stages" of sleep apnea; and
 - c. Dr. Harris' Original Snore Formula tablets eliminate, prevent, or significantly reduce snoring in users of the product.
10. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.
11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

Complaint

12. Through the means described in Paragraph 8, respondent Gerald L. Harris has, expressly or by implication, further made the representations set forth in Paragraph 9.
13. Through the means described in Paragraph 8, respondent Gerald L. Harris has further represented, expressly or by implication, that he possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.
14. In truth and in fact, respondent Gerald L. Harris did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made. Therefore, the representation set forth in Paragraph 13 was, and is, false or misleading.
15. In their advertising and sale of Dr. Harris' Original Snore Formula tablets, respondents have made the representations set forth in Paragraph 9 while failing to disclose or disclose adequately that persons who have symptoms of sleep apnea should consult a physician because sleep apnea is a potentially life-threatening condition. These facts would be material to consumers in their purchase or use of the product. The failure to disclose adequately these facts, in light of the representations made, was, and is, a deceptive practice.
16. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that scientific testing demonstrates that Dr. Harris' Original Snore Formula tablets eliminate, prevent, or significantly reduce snoring in 86% of users. Through the means described in Paragraph 8, respondent Gerald L. Harris has, expressly or by implication, further made this representation.
17. In truth and in fact, scientific testing does not demonstrate that Dr. Harris' Original Snore Formula tablets eliminate, prevent, or significantly reduce snoring in 86% of users.

Complaint

Therefore, the representation set forth in Paragraph 16 was, and is, false or misleading.

18. Through the means described in Paragraph 7, respondents Snore Formula, Inc., Dennis H. Harris, M.D., and Ronald E. General have provided means and instrumentalities to distributors of Dr. Harris' Original Snore Formula tablets, including but not necessarily limited to Gerald L. Harris, to engage in deceptive acts or practices, including the dissemination of the statements set forth in Paragraphs 7 and 8.
19. Respondent Dennis H. Harris, M.D., has made statements as an expert endorser for Dr. Harris' Original Snore Formula tablets, including but not necessarily limited to statements made in the promotional audio cassette attached as Exhibit A (transcribed as Exhibit A-1). These statements include those set forth in Paragraph 7.A.
20. Through the means described in Paragraph 19, respondent Dennis H. Harris, M.D., has represented, directly or by implication, that at the time he made the representations set forth in Paragraph 9, he possessed and relied upon a reasonable basis for such representations, consisting of the actual exercise of his represented expertise in snoring treatment, in the form of an examination or testing of Dr. Harris' Original Snore Formula tablets at least as extensive as an expert in the field would normally conduct in order to support the conclusions presented in the endorsement.
21. In truth and in fact, at the time he made the representations set forth in Paragraph 9, respondent Dennis H. Harris, M.D., did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in Paragraph 20 was, and is, false and misleading.
22. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices,

Complaint

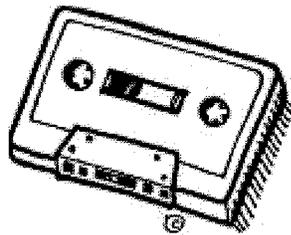
and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

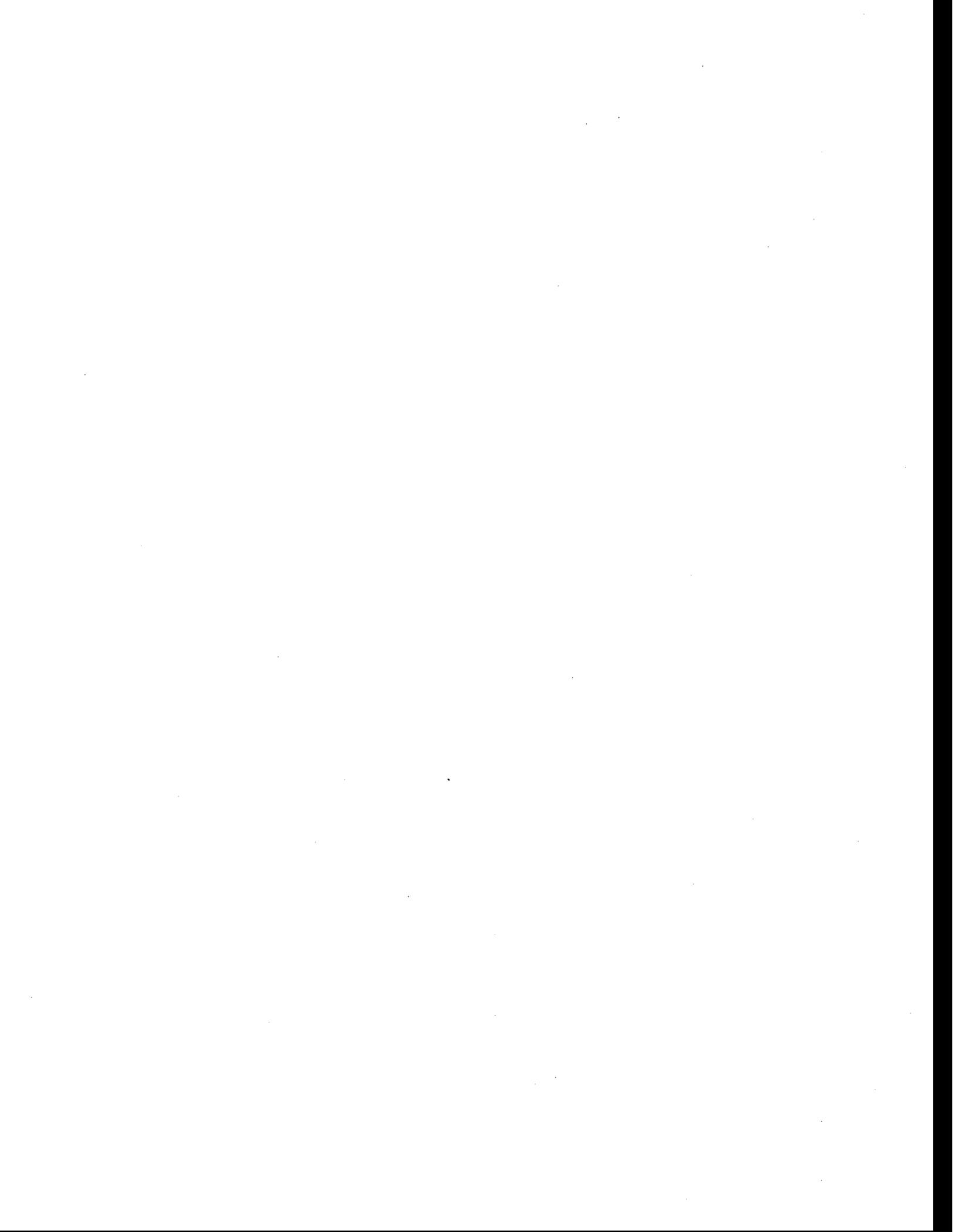
THEREFORE, the Federal Trade Commission this twenty-fourth day of July, 2003, has issued this complaint against respondents.

By the Commission.

Exhibit A

Audiocassette Tape: "The True Facts About Snoring" by
Dennis H. Harris, M.D.





OFFICIAL TRANSCRIPT PROCEEDING

FEDERAL TRADE COMMISSION

MATTER NO. P014205

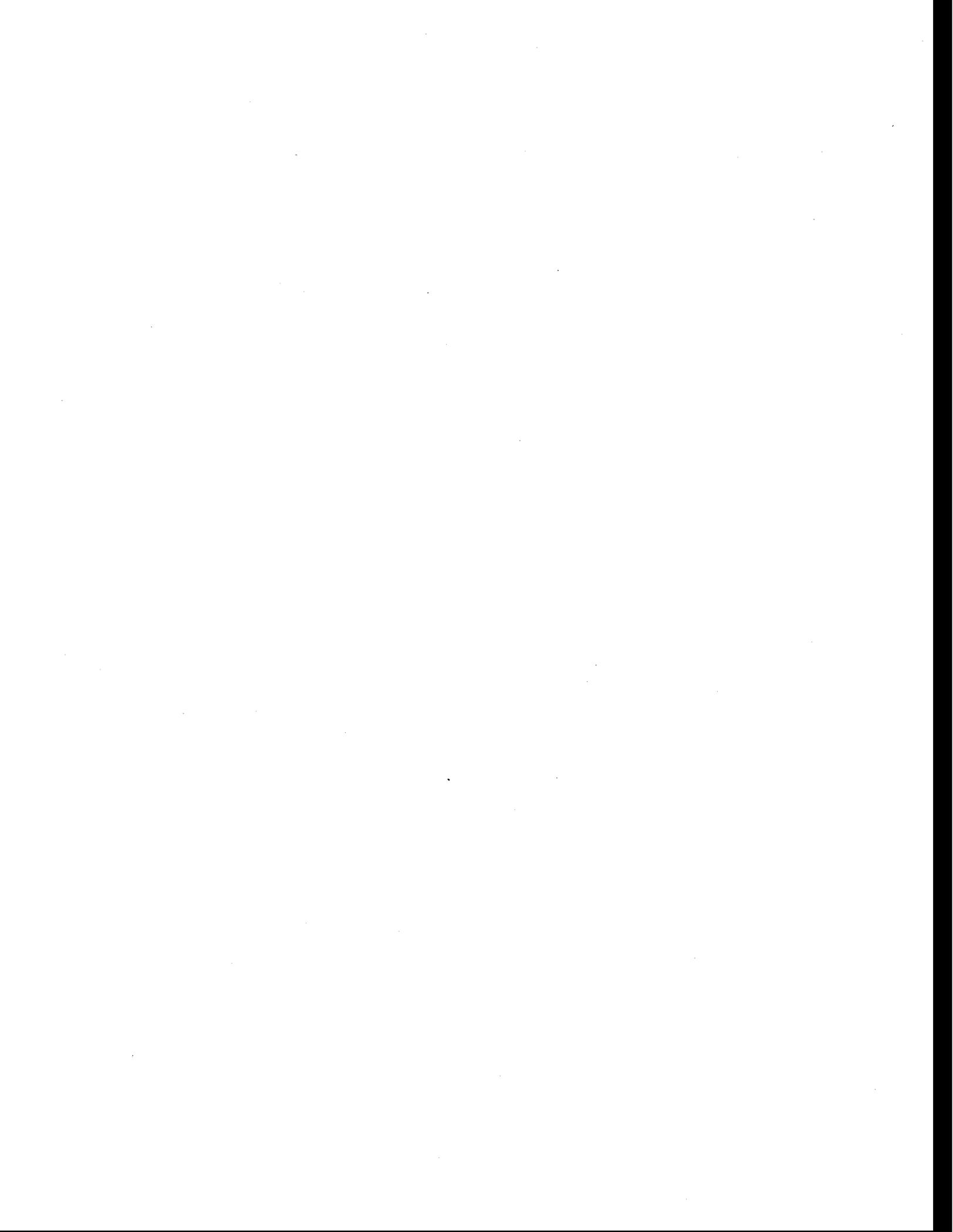
TITLE SNORING AIDS/SLEEPING APNEA

**DATE RECORDED: DATE UNKNOWN
TRANSCRIBED: FEBRUARY 11, 2002**

PAGES 1 THROUGH 30

**THE TRUE FACTS ABOUT SNORING
BY DENNIS H. HARRIS, M.D.
SNORE FORMULA, INC.
TO ORDER, CALL 1-800-442-7436**

**FOR THE RECORD, INC.
603 POST OFFICE ROAD, SUITE 309
WALDORF, MARYLAND 20602
(301)870-8025**



FEDERAL TRADE COMMISSION

I N D E X

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P R O C E E D I N G S

THE TRUE FACTS ABOUT SNORING

(Music playing.)

MALE ANNOUNCER: Welcome to this week's edition of Medical Milestones, the show that brings you information vital to your good health. Our guest this week is Dr. Dennis Harris. Dr. Harris is an expert on snoring. He will be sharing some of the latest information on the causes and treatments for snoring.

And now, here's our host, Chris McKay.

CHRIS MCKAY: Welcome to the program. Did you toss and turn last night because your partner has that irritating habit? If so, you'll want to stay tuned. Whether you were the perpetrator or the victim, you should know that you're not alone.

Millions and millions of Americans are affected by snoring. That's why I asked Dr. Dennis Harris to join us today. Dr. Harris will tell us why we snore, and better yet, what we can do to stop it. Dr. Harris is a graduate of Ohio State University and performed a rotating internship at Grant Hospital in Columbus. He also established the Department of Physical Medicine and Rehabilitation at Scottsdale Memorial Hospital.

Dr. Harris, thanks for joining us today.

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1 DR. DENNIS HARRIS: Well, good morning, Chris.
2 I'm delighted to be here.

3 CHRIS MCKAY: Doctor, why do people snore?

4 DR. DENNIS HARRIS: Well, snoring is really
5 kind of fun to describe because people can actually
6 visualize the process when I talk about it. If you get
7 this mental image of the column of air that we bring in
8 along the back of the nose and throat when we breath, if
9 that goes down smoothly, then, of course, there's no
10 snoring and no problem.

11 On the other hand, if that column of air hits
12 any little partial obstruction along the way, then that
13 airflow becomes turbulent and that disturbed air begins
14 to vibrate those soft tissues that lie in the back of the
15 throat.

16 CHRIS MCKAY: Hmm.

17 DR. DENNIS HARRIS: And then you get (making
18 snoring sound).

19 CHRIS MCKAY: (Laughter).

20 DR. DENNIS HARRIS: Or the noise we not so
21 fondly know as snoring in some cases. You know, it's
22 only in the last few years that we really have started to
23 understand what causes that little partial obstruction.
24 And now we know that in about 90 percent of all of the
25 people who are chronic snorers, that partial obstruction

1 is caused by the nightly accumulation of a lot of
2 respiratory secretions that end up coming up from the
3 lungs and the bronchi and coming down from the sinus
4 cavity and the nasal cavity, and guess where they end up,
5 in the back of the throat.

6 CHRIS MCKAY: Hmm.

7 DR. DENNIS HARRIS: Not only does that cause
8 this mass of secretions that can, by itself, cause a
9 little partial obstruction to the airflow, but in
10 addition to that, what happens is that it irritates the
11 tissues, they become swollen and congested and that
12 narrows down the airway, and that makes the problem occur
13 a whole lot easier.

14 CHRIS MCKAY: You know, Doc, that makes a lot
15 of sense because I've noticed lately that if I fall
16 asleep on my back in the middle of the night, my wife
17 will nudge me and tell me I'm snoring, and I don't really
18 consider myself a snorer.

19 DR. DENNIS HARRIS: Gee, I've got to tell you,
20 you're a brave guy admitting that you snore on the radio.

21 CHRIS MCKAY: (Laughter). I know it, I know
22 it. My friends will never let it down now. (Laughter).

23 DR. DENNIS HARRIS: (Laughter). Well, you
24 know, I've got to tell you, you're not alone, Chris. We
25 keep revising our figures all the time and I have to tell

1 you that our new figures show that up to 40 percent of
2 the entire population are chronic regular snorers. I
3 mean, stop and think about that.

4 CHRIS MCKAY: Wow.

5 DR. DENNIS HARRIS: Right, yeah. This is
6 absolutely incredible. That means that two out of every
7 five people that walk down the street are snorers or 100
8 million people in the United States alone.

9 CHRIS MCKAY: That's unbelievable.

10 DR. DENNIS HARRIS: Absolutely incredible.

11 CHRIS MCKAY: Wow. You know, the -- I know
12 you've done a ton of research in this area, Doctor. What
13 really got you involved, were you a snorer?

14 DR. DENNIS HARRIS: Well, no, I was never a
15 snorer fortunately, but I've got to tell you, not only is
16 my wife a snorer, but I have a daughter, who's now 12,
17 who has been an unbelievable snorer for years.

18 CHRIS MCKAY: . (Laughter).

19 DR. DENNIS HARRIS: I mean, this kid, you can
20 hear her through the entire house, through the walls,
21 through the doors, nothing matters.

22 CHRIS MCKAY: Wow, really sawing the wood, huh?

23 DR. DENNIS HARRIS: Oh, like you wouldn't
24 believe.

25 CHRIS MCKAY: (Laughter). You know, we often

1 joke around about this stuff, but it really isn't a
2 joking matter, is it?

3 DR. DENNIS HARRIS: Oh, no, no. It's not a
4 joking matter at all. I mean, yes, you're right, it's
5 been the subject of a lot of cartoons. You know, through
6 all the years that I've been working with snoring, I
7 still have this little image in one corner of my mind of
8 Dagwood Bumstead lying on his side on the couch with the
9 Zs coming up.

10 CHRIS MCKAY: Right, right.

11 DR. DENNIS HARRIS: So, we always do think
12 about it from the funny side. But I've got to tell you,
13 it is really an absolutely incredible problem. And that
14 problem can be unbelievable in families.

15 CHRIS MCKAY: Oh, yeah, yeah.

16 DR. DENNIS HARRIS: Because this is a
17 significant social problem and much more than people ever
18 realized before. Stop and think about something. You
19 know, I literally talk to people every day about snoring
20 and I talk to families and couples from all over. I talk
21 to thousands of couples every year that have not been
22 able to stay together in the same room with their mate
23 for sometimes anywhere up to five years or even more than
24 that.

25 Well, what happens in relationships -- you

1 know, we live in such a tense time anyway.

2 CHRIS MCKAY: Sure.

3 DR. DENNIS HARRIS: So, relationships are kind
4 of tough.

5 CHRIS MCKAY: Right.

6 DR. DENNIS HARRIS: But, you know, when do we
7 really repair our relationships from all the stresses of
8 normal life is at night.

9 CHRIS MCKAY: Absolutely.

10 DR. DENNIS HARRIS: And, you know, that's when
11 we hold our mate, that's when we touch, when we talk
12 about the little things that bring us closer. It's when
13 we make love. All these things are a little hard to do
14 when you're three doors down the hall.

15 CHRIS MCKAY: (Laughter). Yeah, that's very
16 true. Very true.

17 DR. DENNIS HARRIS: You know, I've always known
18 it was a problem because of dealing with couples and with
19 people who snore. But something really focused this in.
20 About two months ago there was an article that appeared
21 in the popular press that talked about a survey that was
22 done of all the divorces in the country in 1995. You
23 know, we have about six million divorces in the country.

24 CHRIS MCKAY: Yeah.

25 DR. DENNIS HARRIS: Every year. So, what they

1 did was to go through all the applications to find out
2 what the causes were. Amazingly enough, in 2 percent of
3 all the divorce applications, the main cause of the
4 divorce was listed as snoring.

5 CHRIS MCKAY: No.

6 DR. DENNIS HARRIS: Absolutely blew me away.

7 CHRIS MCKAY: Really?

8 DR. DENNIS HARRIS: Yeah, really. And, you
9 know, stop and think about this, this is unbelievable. I
10 mean, this is in one year, 120,000 divorces occur.
11 That's 120,000 marriages wiped out because of snoring in
12 one year. And if that was what was listed as the main
13 cause in all those, in how many others was it a
14 contributing cause or in how many others was it not
15 listed because it wasn't an acceptable reason for divorce
16 in that state?

17 CHRIS MCKAY: Well, you raise a good point.

18 DR. DENNIS HARRIS: I mean, it's just
19 absolutely unreal.

20 CHRIS MCKAY: Wow. Wow. You know, the -- but
21 I'll tell you, I experienced firsthand exactly what
22 you're talking about. And I'll tell you, the first time
23 that, you know, I stayed with my wife in her parents'
24 home, I was amazed -- I was actually awakened in the
25 middle of the night by her younger brother. And, Doc, I

1 got to tell you, it was unbelievable. He was snoring so
2 loud, and he was two rooms down. And I can't even
3 imagine having to stay there every night and listen to
4 that.

5 DR. DENNIS HARRIS: Hey, I'll tell you what,
6 you know, you bring up a real good point, Chris, because
7 you were talking about her younger brother, and I have to
8 tell you, we think of people that snore as being older
9 and maybe overweight and, you know, having a six-pack of
10 beer every night --

11 CHRIS MCKAY: Right.

12 DR. DENNIS HARRIS: -- and all that type of
13 thing.

14 CHRIS MCKAY: Exactly.

15 DR. DENNIS HARRIS: But, you know, that is a
16 stereotype that is really not true. I mean, first of
17 all, younger people snore. Second of all, thin people
18 snore. We always think of this being a guy type of
19 thing. Well, that's not totally true. You know, we talk
20 about 100 million people in the United States being
21 snorers.

22 CHRIS MCKAY: Right.

23 DR. DENNIS HARRIS: Well, guess what, 60
24 percent of those are men, but 40 percent are women.

25 CHRIS MCKAY: Really? That many women?

1 DR. DENNIS HARRIS: Yeah. I mean, that's 40
2 million women that are snorers in the United States.

3 CHRIS MCKAY: Now, see, I wouldn't have thought
4 that. I thought this was mostly a male thing.

5 DR. DENNIS HARRIS: Yeah, I think that most
6 people feel the way -- the way that you did. That's one
7 of the reasons I like to bring this out. The other point
8 that you brought out was a real good one, about kids,
9 because in the old days, we used to take out their
10 tonsils and adenoids all the time. Now, we don't do that
11 and because of that, 25 percent of all pre-adolescent
12 children in the United States are snorers.

13 CHRIS MCKAY: Twenty-five percent?

14 DR. DENNIS HARRIS: Yeah. And not only that,
15 with kids it's even worse because they develop these huge
16 tonsils and adenoids and they literally block off the
17 airflow, and most of these kids actually have a condition
18 called sleep apnea, which is a much more serious problem,
19 and we'll talk about that in a little more detail as the
20 show goes on.

21 But it is a big problem and it really does need
22 to be taken care of in kids.

23 CHRIS MCKAY: Wow. I didn't realize that
24 either.

25 DR. DENNIS HARRIS: Um-hum.

1 CHRIS MCKAY: (Laughter).

2 DR. DENNIS HARRIS: Hey, listen, we're going to
3 bring out all kinds of incredible things during this show
4 that your listeners have never been aware of before.

5 CHRIS MCKAY: Well, that's great. That's
6 exactly why we booked you for this show, Doctor.

7 DR. DENNIS HARRIS: (Laughter).

8 CHRIS MCKAY: We know that you have all kinds
9 of information that we may or may not want to hear.

10 DR. DENNIS HARRIS: Well, there are some bad
11 news things, but we've got some good news things, too

12 CHRIS MCKAY: Well, Doctor, I'm going to
13 interrupt you right there for just a minute. We're going
14 to have to take a break and we're going to come back with
15 some good news from Dr. Dennis Harris right after this
16 break.

17 (Brief pause.)

18 CHRIS MCKAY: And we're back. Before the
19 break, we talked a little bit about the difference
20 between men and women. Men do snore more than women, but
21 a lot of women snore, and it can be a problem for
22 youngsters, too. Most of the time, as we get older, it
23 becomes more of a problem.

24 Dr. Dennis Harris is with us today and we
25 talked about, and Dr. Harris has addressed, what causes

1 many of us to snore. And now, we're going to talk about
2 some good news out there that can help. Before the
3 break, again, we had mentioned a little bit about the
4 number of people that snore and the difference between
5 men and women.

6 Doctor, you touched on an interesting thought
7 in that I really thought it was only older people that
8 were affected.

9 DR. DENNIS HARRIS: You know, you bring up a
10 very good point. We do tend to snore more and more
11 people snore the older we get. Let me give you an
12 example, though. If you took a group of 100 people, 50
13 men and 50 women, that were age 20, 20 years old, and you
14 assessed all of them, what you would really find
15 typically is that 5 percent of women were chronic snorers
16 and 29 percent of the men were chronic snorers. So,
17 there's a big difference at that age.

18 CHRIS MCKAY: So, there's definitely more men.

19 DR. DENNIS HARRIS: Right. By a long ways. As
20 you follow that group up to age 50, by that age, 40
21 percent of all of the women will now be chronic snorers
22 and 60 percent of all the men will be chronic snorers,
23 and by age 70, 70 percent of both sexes will be chronic
24 regular snorers.

25 CHRIS MCKAY: Wow.

1 DR. DENNIS HARRIS: Yeah. So, you can see that
2 more people will join that group of chronic snorers as
3 they age and not only that, what those figures don't show
4 is that very definitely the snoring progressively gets
5 worse as time goes on.

6 CHRIS MCKAY: So, there is -- that's what I was
7 just going to ask you. There's a progression then to
8 snoring.

9 DR. DENNIS HARRIS: Oh, yeah, no question about
10 it. You know, we used to think -- that's a major point
11 that I want to bring out. We used to think that there
12 were a lot of different kinds of snorers. For example,
13 Chris, you talked earlier in the show about the fact that
14 you snore on and off, you know.

15 CHRIS MCKAY: Right.

16 DR. DENNIS HARRIS: And usually just on your
17 back.

18 CHRIS MCKAY: Right.

19 DR. DENNIS HARRIS: But let me tell you, you
20 are an amateur. (Laughter).

21 CHRIS MCKAY: (Laughter).

22 DR. DENNIS HARRIS: You're a beginning snorer.

23 CHRIS MCKAY: Okay. (Laughter).

24 DR. DENNIS HARRIS: And typically, that is the
25 way people start to snore. They typically snore only

1 occasionally, usually on their backs and usually with
2 their mouth open and the snoring is kind of mild to
3 moderate.

4 CHRIS MCKAY: Um-hum.

5 DR. DENNIS HARRIS: There are times when it
6 gets a little worse. But most of the time it's mild to
7 moderate. Well, snoring is kind of like playing the
8 violin, you know, the more you practice, the better you
9 get.

10 CHRIS MCKAY: (Laughter).

11 DR. DENNIS HARRIS: (Laughter). And sure
12 enough, as time goes on, that individual will begin to
13 snore more nights out of a week, the time during each
14 night that that person will snore will become longer. It
15 will become louder, and eventually, that person will be
16 able to snore in any position.

17 CHRIS MCKAY: (Laughter).

18 DR. DENNIS HARRIS: Yeah. I mean, even on
19 their stomach, no question. Now, the incredible part of
20 that is that, at that point, 20 percent of all those
21 people that are chronic snorers will then go on to
22 progress to a very serious problem called sleep apnea.

23 CHRIS MCKAY: Now, I've heard of this. As a
24 matter of fact, a friend of mine has this.

25 DR. DENNIS HARRIS: Oh, yeah, it's a very, very

1 serious medical problem, and it's been recognized in that
2 regard for many, many years. It is, for your listeners
3 who aren't familiar with it, it is the condition in which
4 the snorer actually stops breathing for periods of
5 anywhere from 10 or 15 seconds all the way up to even a
6 minute or more, and does it many times every hour.

7 CHRIS MCKAY: And this is very scary. This is
8 a serious, serious problem.

9 DR. DENNIS HARRIS: When you said scary, it's
10 not only scary for the person, but stop and think of the
11 person's mate. I mean, I have talked to men or women who
12 literally stay up almost the entire night because every
13 time their mate stops breathing, they are absolutely
14 scared to death that they won't start again.

15 We used to think in medicine that people
16 developed sleep apnea and that was a separate condition.
17 But like I just pointed out, it is not a separate
18 condition, it is the end result of somebody who first
19 begins to snore progressing all the way through these
20 different stages and ending up with sleep apnea.

21 CHRIS MCKAY: Yeah (inaudible).

22 DR. DENNIS HARRIS: Yeah.

23 CHRIS MCKAY: Now, Doctor, we've spent some
24 time here talking about the problem. You actually have
25 come up with a solution, is that correct? You've created

1 a product that can help with snoring?

2 DR. DENNIS HARRIS: I have, and it has this
3 very unique name. It's called Dr. Harris' Snore Formula.
4 (Laughter).

5 CHRIS MCKAY: (Laughter). Imagine that.

6 DR. DENNIS HARRIS: It took a whole crew to
7 figure this one out. (Laughter).

8 CHRIS MCKAY: (Laughter).

9 DR. DENNIS HARRIS: Anyway, it's really neat.
10 It -- not because I created the product, but because of a
11 number of other things. First of all, it is 100 percent
12 natural, and I want to bring this out. It is not a
13 medication. A medication -- you know, I've been a doctor
14 for 30 years. I've prescribed my share of medications
15 for sure.

16 CHRIS MCKAY: Sure.

17 DR. DENNIS HARRIS: But, you know, through the
18 years, we've always been aware of the fact that
19 medications have become stronger and stronger, they've
20 become more and more effective, but they also have become
21 more dangerous.

22 CHRIS MCKAY: Hmm.

23 DR. DENNIS HARRIS: What do I mean by that?
24 Well, there are more side effects. The side effects have
25 typically become more serious through the years, and

1 interestingly enough, people become more and more
2 allergic to medicines. So, even medicines that we use
3 for allergies, sometimes people become allergic to.

4 CHRIS MCKAY: Right, right. Many side effects
5 from what I understand.

6 DR. DENNIS HARRIS: Oh, yeah.

7 CHRIS MCKAY: Yeah.

8 DR. DENNIS HARRIS: And I -- I'm going to
9 interrupt and break my train of thought for one reason.

10 CHRIS MCKAY: Okay.

11 DR. DENNIS HARRIS: I have to tell you that
12 there was a recent publication -- in fact, it was
13 Newsweek, that had printed a special edition at the end
14 of the 1997, kind of summarizing the year and all that.

15 CHRIS MCKAY: Um-hum.

16 DR. DENNIS HARRIS: And they were talking
17 about, in one section, medicine. They brought out the
18 fact that in the United States, every year, approximately
19 21,000 people die of AIDS --

20 CHRIS MCKAY: Um-hum.

21 DR. DENNIS HARRIS: -- approximately 24,000
22 people die of homicide. 63,000 people die every year
23 from medications.

24 CHRIS MCKAY: From medications?

25 DR. DENNIS HARRIS: From medications that they

1 take.

2 CHRIS MCKAY: Wow.

3 DR. DENNIS HARRIS: Unbelievable.

4 CHRIS MCKAY: And these aren't overdoses?

5 DR. DENNIS HARRIS: No, no. These are people
6 who take it in the normal dosage.

7 CHRIS MCKAY: Wow.

8 DR. DENNIS HARRIS: 63,000 people every year.
9 That's more people than die in automobile accidents, you
10 know. We only have 50,000 -- that's more people than
11 that died in the entire Vietnam War.

12 CHRIS MCKAY: Oh, that puts it in perspective.

13 DR. DENNIS HARRIS: Yeah. And we do -- and
14 that's how many people die from taking their normal
15 medication every year. So, when I say this is a natural
16 product, that has a lot of implications, you know. We
17 don't get the kind of side effects and allergies with
18 natural products that we see with medications.

19 CHRIS MCKAY: Yeah.

20 DR. DENNIS HARRIS: You know, for example, in
21 Dr. Harris' Snore Formula, we've had over 100,000 people
22 using the product. We have never yet had the first
23 report of any kind of side effects or allergies.

24 CHRIS MCKAY: Oh, that's great. How long has
25 the product been out, Doc?

1 DR. DENNIS HARRIS: It's been out about two
2 years on the marketplace.

3 CHRIS MCKAY: Um-hum.

4 DR. DENNIS HARRIS: And as I said, we've had
5 about 100,000 people that have used the product. I
6 did -- I did a lot of testing for about two years prior
7 to the time that we put it on the market. I tested it on
8 about 220 patients and, you know, we wanted to see how
9 effective it really was.

10 CHRIS MCKAY: Sure. And the results are?

11 DR. DENNIS HARRIS: The results were wonderful.
12 We were hoping that it was maybe going to help 50 percent
13 of the people or so.

14 CHRIS MCKAY: Yeah.

15 DR. DENNIS HARRIS: In reality, 86 percent of
16 the people that were taking this formula had really good
17 to excellent results.

18 CHRIS MCKAY: Oh, that's fantastic.

19 DR. DENNIS HARRIS: Yeah. And that's really
20 kind of held up -- we run about 86 to 90 percent of the
21 people that have good results that take it.

22 CHRIS MCKAY: So, these are capsules that you
23 take?

24 DR. DENNIS HARRIS: Well, they're actually a
25 little tablet.

1 CHRIS MCKAY: Okay.

2 DR. DENNIS HARRIS: It's taken by weight. It's
3 really a convenient way, an easy way to solve the
4 problem. You just take them about 30 minutes before you
5 go to bed so that they can be absorbed and be ready to
6 work when you go to sleep. And the way it works is
7 absolutely neat. It is composed of four natural
8 digestive enzymes and a variety of herbs. The enzymes
9 begin to do their job. They literally start to digest or
10 breakdown all of these respiratory secretions that are in
11 the back of the throat and they allow the body to absorb
12 them and remove them, and the herbs reduce the tissue
13 swelling.

14 So, between the two things, what we've been
15 able to do is to open up the airway and smooth out the
16 airflow and then the snoring goes away.

17 CHRIS MCKAY: Interesting. We're going to take
18 a break right here and come back with more from Dr.
19 Harris right after this break.

20 (Brief pause.)

21 CHRIS MCKAY: We're back with Dr. Dennis
22 Harris, who has introduced help for millions and millions
23 of Americans who have a problem or the husband or wife or
24 somebody they live with has a problem with snoring.

25 Doctor, I'd like to go back and touch on

1 something that we had talked about just a bit earlier,
2 and that was about really the -- you had talked briefly
3 about the progression of snoring. And I got to tell you,
4 I had mentioned earlier, has sleep apnea. And he
5 actually wears a breathing apparatus to -- as I
6 understand, to keep the airway open.

7 DR. DENNIS HARRIS: That's called a CPAP
8 machine and that stands for continuous positive airway
9 pressure. Let me -- let's talk -- let's go back and talk
10 for a moment about this progression again.

11 CHRIS MCKAY: Um-hum.

12 DR. DENNIS HARRIS: And what happens
13 mechanically to people when they snore.

14 CHRIS MCKAY: Because that can be the result at
15 the end, right?

16 DR. DENNIS HARRIS: Yeah.

17 CHRIS MCKAY: Having to wear something like
18 that?

19 DR. DENNIS HARRIS: Yeah, it really is. And
20 let me tell you, we talked about what's -- you know, how
21 snoring -- what causes snoring and all that and then
22 about the partial obstruction.

23 Well, what really happens is that -- and you
24 can imagine this if you've ever heard somebody snore.
25 When that air hits that little partial obstruction,

1 you're really straining to try and get air past that.
2 And when you're doing that, you cause a little bit of a
3 vacuum at that point of obstruction. And since that
4 point of obstruction is the same almost every time you
5 snore, that strain -- that mechanical strain that's
6 caused by the vacuum is put on the airway at the same
7 place every time you snore.

8 CHRIS MCKAY: So, the result is it starts to
9 collapse?

10 DR. DENNIS HARRIS: Yes, that's exactly right.

11 CHRIS MCKAY: Wow.

12 DR. DENNIS HARRIS: Over the years, you start
13 to get structural weakness in the airway and it begins to
14 literally start to collapse and that's why it progresses
15 to sleep apnea, because when it gets to the point where
16 it is so weak it literally collapses down and absolutely
17 blocks the airflow.

18 CHRIS MCKAY: Wow.

19 DR. DENNIS HARRIS: Yeah. It's absolutely
20 unreal. And, you know, when I describe it like this, it
21 becomes very logical to people and it's amazing to me
22 that medically we never saw this for so many years. But
23 that is exactly what occurs.

24 And when you get to that point where the sleep
25 apnea is due to this kind of a structural weakness, which

1 then gets worse and worse --

2 CHRIS MCKAY: Um-hum.

3 DR. DENNIS HARRIS: -- then, you know, it's not
4 a matter of taking anything for it, it's a matter of
5 doing something about it. And the one thing that is the
6 most common remedy is the CPAP machine.

7 CHRIS MCKAY: Hmm.

8 DR. DENNIS HARRIS: And you put that in -- it's
9 a mask that is worn over the face. Air is forced under
10 pressure continuously all the way down through the
11 airway, and what you're doing is forcing air down with
12 enough pressure that it pushes the airway open and keeps
13 it that way.

14 Well, as you can imagine, that's not exactly
15 the most wonderful thing to have to do every night all
16 night.

17 CHRIS MCKAY: I can't imagine having to sleep
18 with that. Now, Doctor, will your product help in those
19 instances?

20 DR. DENNIS HARRIS: What we find is that in the
21 early stages of sleep apnea, we do have a high rate of
22 success. But once it reaches a moderate to severe level,
23 I mean, that really is a structural problem that demands
24 a physical solution to it.

25 CHRIS MCKAY: So, what you're really saying is

1 people have to understand that they need to take care of
2 this early on.

3 DR. DENNIS HARRIS: That's the good news.

4 CHRIS MCKAY: Okay.

5 DR. DENNIS HARRIS: That's the good news,
6 exactly. You know, we didn't have good ways to handle
7 snoring for a long period of time, and so, people did go
8 through this progression. But the good news is that you
9 can stop this. You can absolutely stop this progression.
10 If you go ahead and -- well, let's talk about some of the
11 medical things that go on with snoring. Can we do that
12 for a moment?

13 CHRIS MCKAY: Sure, sure.

14 DR. DENNIS HARRIS: Okay. We didn't realize
15 for many years that snoring was a real medical problem.
16 All we thought about was what happened to people once
17 they had developed sleep apnea and we didn't think any of
18 these other problems occurred in just the snorer.

19 Now, for the first time last year, medical
20 organized medicine actually came out and said, snoring is
21 a true medical problem.

22 CHRIS MCKAY: So --

23 DR. DENNIS HARRIS: Because they're finally
24 beginning to understand the progression.

25 CHRIS MCKAY: So, it's taken this long?

1 DR. DENNIS HARRIS: Yeah. Only about 4,000
2 years, but that's all right. (Laughter).

3 CHRIS MCKAY: (Laughter).

4 DR. DENNIS HARRIS: We're a little slow in
5 organized medicine. (Laughter).

6 CHRIS MCKAY: (Laughter).

7 DR. DENNIS HARRIS: Anyhow, what are some of
8 the things that really occur? You know, they started
9 gathering more statistics about snoring, and lo and
10 behold, what they started to realize was that there are
11 both short-term and long-term problems, medical problems
12 associated with snoring. For example, the long-term
13 medical problems are a 400 to 500 percent increase in the
14 level of risk of developing heart attacks, strokes and
15 high blood pressure compared to non-snorers.

16 CHRIS MCKAY: Wow.

17 DR. DENNIS HARRIS: I mean, this is a huge risk
18 factor. That's almost at a rate equivalent to smoking a
19 couple of packs of cigarettes a day or something like
20 that, okay? So, this is a big risk factor.

21 CHRIS MCKAY: Yeah.

22 DR. DENNIS HARRIS: Well, they started coming
23 out with these statistics and they said, holy cow, why is
24 this happening. Well, what they began to do is to
25 measure and investigate various aspects of the problem

1 and they found that when people snore, the level of
2 oxygen in the blood stream drops down significantly in a
3 vast majority of these snorers. And so, what's
4 happening, all of the blood goes to all the vital organs,
5 the brain, the heart, the liver, the kidneys and so
6 forth, and guess what, there's a lower than normal level
7 of oxygen that occurs.

8 Well, that means that those organs are being
9 oxygen-deprived and oxygen, of course, is our critical
10 element for -- to keep the cells functioning normally and
11 alive.

12 CHRIS MCKAY: Right.

13 DR. DENNIS HARRIS: So, over a period of time,
14 little bits of damage begin to occur and as they
15 accumulate more and more, then eventually the person
16 becomes symptomatic and develops either heart attacks or
17 a stroke or high blood pressure.

18 CHRIS MCKAY: Wow.

19 DR. DENNIS HARRIS: Yeah, it's a big thing.
20 They just did a big study that was published in a medical
21 journal called Sleep, which is where all the sleep
22 disorder reports come out, and this study demonstrated
23 that chronic snorers have a 300 percent higher risk of
24 being involved in an automobile accident in a five-year
25 period compared to non-snorers, and a 700 percent higher

1 risk of being involved in multiple automobile accidents
2 over a five-year period.

3 CHRIS MCKAY: Well, great. (Laughter).

4 DR. DENNIS HARRIS: I mean, yeah, you know,
5 that's not the good news. That's the bad news.
6 (Laughter).

7 CHRIS MCKAY: (Laughter). Well --

8 DR. DENNIS HARRIS: (Laughter). But again, you
9 know, the good news is we can stop that whole thing from
10 getting to that point.

11 CHRIS MCKAY: That's great. Dr. Harris, you've
12 convinced me. I'm going to put your product to the test
13 and try it myself. I'd encourage my listeners to do the
14 same. What an easy solution. No surgery and the result
15 is a peaceful night's sleep and it sounds like you're
16 going to continue living after that as well.

17 We're out of time. Doctor, any parting
18 thoughts?

19 DR. DENNIS HARRIS: One real parting thought.
20 If you don't carry anything away, if you hear -- if
21 you're a listener and you haven't carried anything away
22 that we've talked about, remember one thing, we have the
23 opportunity now of stopping this progression of snoring,
24 and when you stop it, at that point, the healing power of
25 your body takes over, and eventually, all of these -- all

1 of this damage repairs itself and you get back to normal.

2 Don't wait. Pick up the phone today, try our
3 product. It is absolutely without risk to you because we
4 have a 100 percent money back guarantee. You have
5 nothing to lose but your snoring.

6 CHRIS MCKAY: You heard it here, first. Again,
7 I encourage anyone who's experiencing snoring to pick up
8 the phone and call Dr. Harris. Doc, we're going to have
9 you back again. We covered a lot of material, I know
10 there's a lot more. Have a great day and take care.

11 And that's it for this week's show. We'll be
12 back next week.

13 (Music playing.)

14 (Both sides of the audiotape contain the same
15 recording.)

16 (The taping was concluded.)

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C E R T I F I C A T I O N O F T Y P I S T

MATTER NUMBER: P014205CASE TITLE: SNORING AIDS/SLEEPING APNEATAPING DATE: DATE UNKNOWNTRANSCRIPTION DATE: FEBRUARY 11, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the tapes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

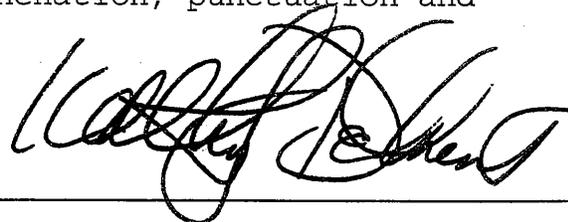
DATED: FEBRUARY 11, 2002



ELIZABETH M. FARRELL

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.



KATHY J. DE MENT

Snoring is a condition that is associated with serious and potentially life-threatening medical problems. Snorers have a much higher risk of heart attacks, high blood pressure, and strokes. Snoring also produces sleep disturbances in the person snoring and their mate. Snoring also leads to serious social problems and broken relationships.

DIRECTIONS:

Take 30-45 minutes before bedtime.
Take by weight as follows:

125 lbs or less, take one tablet.
125-220 lbs, take two tablets.
Over 220 lbs, take three tablets.

Fast Results:

Take double the usual dose for the first 3 weeks. When maximum results are obtained, lower the nightly dosage by 1/2 caplet each week to achieve the lowest dose that controls snoring. Keep out of reach of children. If pregnant, check with your physician before use.

INGREDIENTS:

Acerola, Amylase, Cayenne Pepper, Cellulase, Echinacea, Elderberry, Eucalyptus, Fenugreek, Lipase, Protease, Red Clover, Rose Hips, Slippery Elm, Yarrow.

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Dr. Harris' Original Snore Formula

2

A UNIQUE COMBINATION OF ALL
NATURAL HERBS AND ENZYMES
THAT GENTLY WORK TOGETHER TO
PREVENT SNORING

100% Natural

Easy to take tablet

No side effects
or allergies

Doctor Formulated
and tested

86% of those using
this formulation had
good to excellent
results

**A REPORT FROM:
DENNIS H. HARRIS, M.D.**

OCCURRENCE:

Statistics have proven that over 40% of the adult population are chronic, regular snorers!

DANGERS OF SNORING:

- Snorers have a markedly higher risk of developing heart attacks, high blood pressure, or strokes.
- Snoring often produces daytime sleepiness or daytime fatigue.
- Snorers have a much higher rate of automobile accidents than non-snorers.
- Snoring causes sleep disturbances that lead to increased anxiety, hyper-irritability, decreased memory, and poor concentration.

**SOCIAL IMPACT OF
SNORING:**

- Snoring often causes resentment between partners, leading to a loss of intimacy and deterioration of relationships.
- Increased irritability leads to failing relationships at home and among co-workers.
- Poor memory and concentration produce decreased work performance.

CAUSE OF SNORING:

Most cases of snoring are due to the nightly accumulation of secretions in the back of the throat and the associated tissue swelling. These factors produce a partial airflow obstruction and narrowed airway, allowing vibration of the soft tissues in the throat.

**How Dr. Harris' Original
Snore Formula™ Works:**

The unique combination of natural enzymes metabolizes the secretions, allowing the body to absorb them. The herbs reduce the tissue swelling. The result is to open the airway, smooth out the airflow and eliminate the snoring.

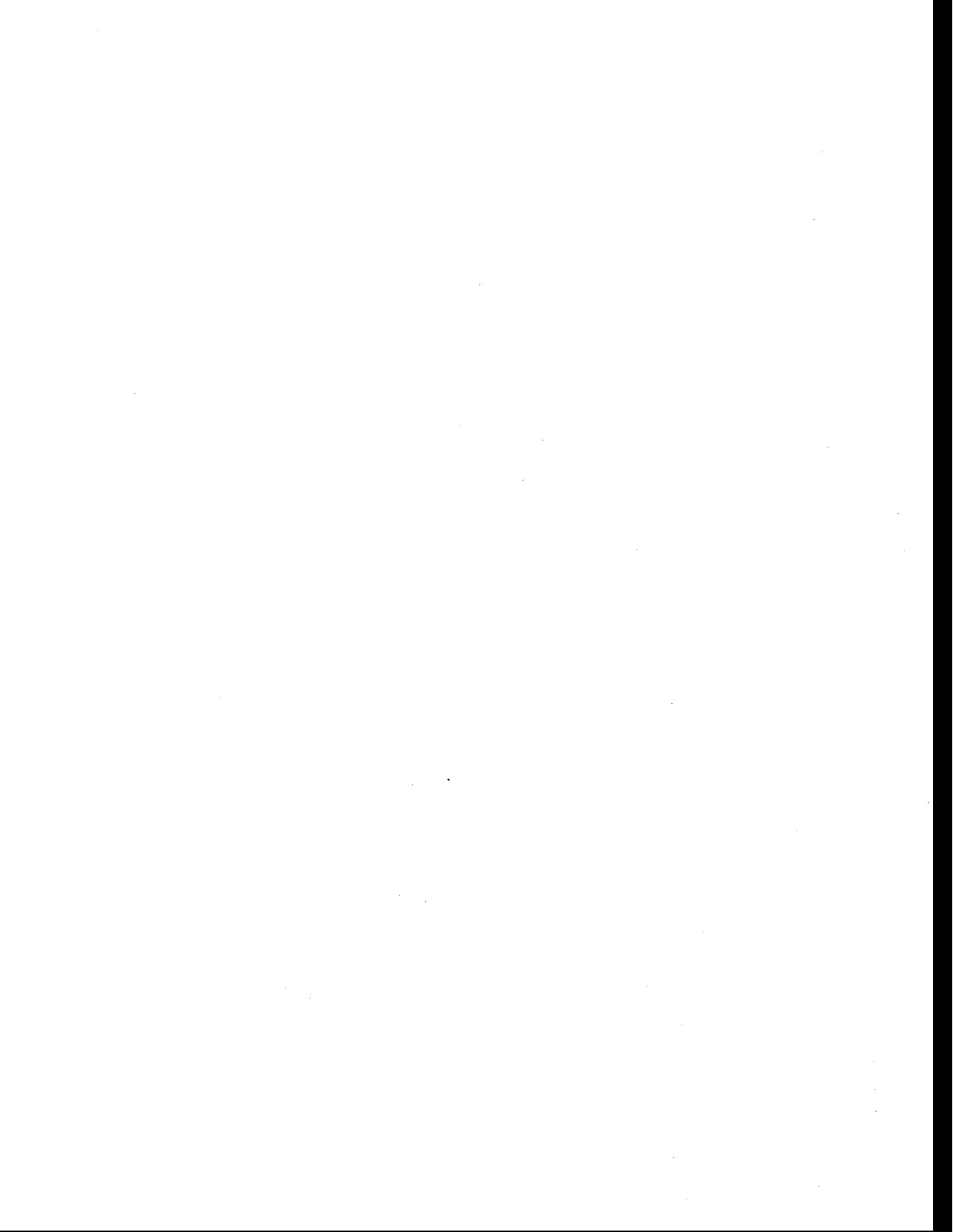
**About Dr. Harris' Original
Snore Formula™:**

This unique formulation was created by Dennis H. Harris, M.D., a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results. Good Housekeeping magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users. Over 40,000 people have used the product over the past 12 months with good results.

Dr. Harris' Original

SNORE FORMULA

Product Information Booklet



WHY SHOULD I WORRY ABOUT SNORING?

Although snoring has been the object of jokes and cartoons, medical science has determined that snoring is associated with serious medical conditions. Snorers are known to have a much higher rate of heart attacks, strokes and high blood pressure than non-snorers. The risk of developing these medical problems increases the longer that a person snores and the more severely they snore. Therefore, it is critical that snoring be brought under control and kept under control indefinitely. By keeping the snoring under control, the risk factors for all of these serious medical conditions gradually decrease toward normal over a period of years.

In addition, studies done at Stanford University and other institutions have shown that snorers have a higher rate of automobile accidents than non-snorers! Why would this happen? Snoring is known to cause reduced oxygen flow to the brain and other organs, resulting in daytime fatigue or sleepiness, slower reflexes and reduced attention span. These factors cause impairment of our ability to concentrate on road and traffic conditions.

WHAT ARE SOME OF THE OTHER EFFECTS OF SNORING?

Snoring is often a significant factor in relationships, causing disturbed sleep patterns, daytime fatigue and hyper-irritability in the non-snoring partner. In more extreme cases, the partners have to sleep in separate bedrooms. This produces increasing resentment, loss of intimacy and, eventually, deterioration of the relationship.

These factors also cause anxiety and depression, often leading to failing relationship with friends and co-workers, as well as reduced work performance.

WHO SNORES?

Medical authorities have estimated that up to 40% of the entire population are chronic, regular snorers.

Snoring increases in severity and prevalence with increasing age. For example, an average 20 year old group would include 5% of females and 29% of males that are chronic snorers; an average 50 year old group would include 40% of females and 60% of males that are chronic snorers; and an average 70 year old group would include 70% of all males and females that are chronic snorers.

WHAT CAUSES SNORING?

Our respiratory system constantly produces secretions in the nasal cavity, sinuses, bronchi and lungs. Although we easily dispose of these secretions during the day, the secretions begin to accumulate in the back of the throat at night when we lie down in the horizontal position. These secretions begin to irritate the surrounding tissues, producing congestion and swelling. These factors produce a partial obstruction to the airflow, resulting in airflow turbulence which vibrates the soft tissues in the back of the throat and produces the sound of snoring. The narrowing of the airway due to the tissue swelling causes further relaxation of the soft tissues, allowing snoring to occur easier. More than 85% of the cases of snoring are due to these factors!

The remaining cases of snoring are due to other conditions such as deviation of the nasal septum, nasal polyps, malformations of the mandible (lower jaw), excessively long uvula or excessively long tongue.

WHAT MAKES SNORING WORSE?

There are many factors that have been identified which may increase the frequency and/or severity of snoring. These include the following:

1. Obesity. Excess weight gain results in the deposition of fat in all tissues, including those around the mouth and throat. This produces narrowing of the airway, loosening of the soft tissues and allows snoring to occur easier.
2. Alcohol Consumption at Night. Consuming the equivalent of more than 2 drinks through the evening results in excess relaxation of the soft tissues in the back of the throat. These tissues then vibrate easier, producing more frequent and more severe snoring.
3. Increased Respiratory Secretions. This condition may arise because of many factors, including cigarette smoking, chronic bronchitis, allergies, chronic sinusitis, chronic rhinitis (nasal congestion) and mucous-producing foods eaten in the evening, such as dairy products.

HOW DOES DR. HARRIS' ORIGINAL SNORE FORMULA® WORK?

This unique formulation includes a secret combination of 100% natural enzymes and herbs. These compounds are all extracted from plants and are repeatedly tested to insure the highest quality and potency.

The enzymes act to digest the secretions, allowing the body to metabolize and absorb them. The herbs reduce the tissue swelling and congestion. The result is that the airway is opened, the airflow is smoothed out and the snoring is markedly decreased or eliminated.

HOW SHOULD I TAKE DR. HARRIS' ORIGINAL SNORE FORMULA®?

If you are to derive the maximum benefits from the product, it must be taken correctly.

The dosage is initially determined by weight. If you weigh 125# or less, take 1 caplet, 125#-220# takes 2 caplets, and over 220# take 3 caplets.

We have found that each individual is unique, and therefore the dosage will vary considerably. To obtain the fastest and best results, we highly recommend that you take double the usual starting dosage for the first three weeks. After the maximum benefit is obtained, lower the dosage by one half caplet each week until you achieve the lowest dose at which satisfactory results are still maintained. Continue using that lower dosage as your maintenance dosage indefinitely.

Higher dosages may produce some dryness in the nose and throat. This only indicates that Dr. Harris' Original Snore Formula® is working well for you! A humidifier will relieve the dryness if it is a concern.

There are many things that you can do to increase the effectiveness of the product, including the following:

1. Take Dr. Harris' Original Snore Formula® 30-45 minutes before bedtime.
2. Be sure to take Dr. Harris' Original Snore Formula® on an empty stomach. Do not eat for two hours before taking the product.
3. Avoid dairy products, such as milk, butter, cheese, etc. for four hours before bedtime, as they may increase the production of respiratory secretions.
4. Severe allergies, smoking or evening alcohol consumption tend to make snoring worse. These conditions may require you to increase the recommended dose of Dr. Harris' Original Snore Formula® by one half to one caplet in order to obtain satisfactory results.

Life style changes, including weight loss, stopping cigarette smoking and reducing evening alcohol consumption, will not only improve snoring control but also lead to better health!

HOW SAFE IS DR. HARRIS' ORIGINAL SNORE FORMULA® ?

Since Dr. Harris' Original Snore Formula® is a 100% natural formulation, we have experienced none of the all too frequently seen side effects and allergic reactions commonly associated with over the counter and prescription medications. In fact, after two years of clinical studies and tens of thousands of satisfied users, we have no reports of side effects, allergies or intolerance of the product.

Furthermore, thousands of people now using the product are taking other medications as well. To date, we have received no reports of cross-reactions with any other medication. However, if this is a concern, please check with your physician.

Although the product is extremely safe, you should check with your physician prior to taking the product if you are pregnant or a nursing mother.

CAN I GIVE DR. HARRIS' ORIGINAL SNORE FORMULA® TO MY CHILD?

Since we no longer remove children's tonsils and adenoids routinely, it is estimated that 20-25% of all children are now chronic snorers. Many of these children also suffer from sleep apnea, a condition in which the person completely stops breathing for up to 30 seconds or more several times each hour. This is a serious medical condition!

Dr. Harris' Original Snore Formula® is being taken by hundreds of children across the country and appears to be quite safe.

The recommended dosage for children weighing 65-100# is one caplet and for those weighing less than 65#, one half caplet.

We advise you to check with your physician before giving Dr. Harris' Original Snore Formula® to children younger than six years of age.

HOW EFFECTIVE IS DR. HARRIS' ORIGINAL SNORE FORMULA®?

Two years of clinical testing by Dennis Harris, MD on 200 chronic snorers produced good to excellent results in 86% of the test subjects taking this formulation.

Good Housekeeping, in an independent study, demonstrated that the formulation used in Dr. Harris' Original Snore Formula® produced major improvement in the vast majority of test subjects.

Reports from those using the product indicate a similar level of satisfaction.

WILL I HAVE TO TAKE DR. HARRIS' ORIGINAL SNORE FORMULA® FOREVER?

Like many medical problems, such as heart disease, hypertension and diabetes, snoring is a condition that can be controlled but not cured. Therefore, once you have determined your maintenance dosage level, you must take that dosage regularly and indefinitely.

We have found that many users of Dr. Harris' Original Snore Formula®, after maintaining good results for 5-6 months, are able to either gradually reduce their dosage even further, take Dr. Harris' Original Snore Formula® every other night, or both.

It is vitally important that you keep your snoring under control indefinitely. The longer your snoring is controlled, the lower your risk factors for heart attacks, strokes and high blood pressure.

ARE THERE ANY OTHER BENEFITS OF DR. HARRIS' ORIGINAL SNORE FORMULA® ?

The top quality variety of herbs and enzymes used in Dr. Harris' Original Snore Formula® have many other significant benefits.

Recent studies suggest that protease may actually help remove cholesterol from partially clogged arteries, thereby restoring circulation.

Protease, lipase and amylase work together to help relieve heartburn and gastric irritation, improving digestion.

The herbs are known to produce the following benefits:

1. Acerola. This South American cherry contains the highest concentration of natural Vitamin C known. It is helpful in reducing inflammation, preventing and treating upper respiratory infections, acts as a stimulant to the immune system and is a powerful anti-oxidant.
2. Eucalyptus. Studies have shown that this herb is effective in killing the flu virus and many types of bacteria. It is also widely used in the treatment of respiratory conditions.
3. Elderberry. This herb is widely used to reduce fever, reduce inflammation, induce pain relief, treat colds, bronchitis and asthma, and decrease allergic symptoms.
4. Yarrow. This herb is known to help cleanse the blood of impurities, including uric acid. It is useful in the in the treatment and prevention of

- gout, digestive problems, nausea, and fever. It is a powerful virus inhibitor, and it is used in the treatment of colds and flu.
5. Slippery Elm. This herb is used to promote digestion, treat intestinal ulcers, neutralize excess stomach acidity and absorb foul gases. It is also used in the treatment of bronchitis and cough.
 6. Echinacea. This marvelous herb is a natural antibiotic, anti-viral and anti-inflammatory compound. It is also a potent blood cleanser and rebuilder, as well as a powerful immune system stimulant.
 7. Red Clover. This herb has been used by some physicians in the treatment of cancer. It is an excellent blood purifier and is widely used in the treatment of liver congestion.
 8. Rose Hips. This herb contains high levels of Vitamin C and bioflavonoids. It is an excellent natural anti-oxidant, builds and strengthens body tissues and is useful in building and maintaining a good blood vascular system.
 9. Cayenne. This herb has many beneficial effects. It aids in lowering serum cholesterol and serum triglycerides, also decreasing LDL cholesterol and therefore decreasing the risk of heart attacks and strokes. It speeds fat metabolism, burning off excess fat more rapidly. It increases heart action without increasing blood pressure, thereby improving circulation and acting as a general body stimulant. It has high Vitamin A content, promoting normal vision and healthy immunity. It increases the effectiveness of all other herbs by aiding in the more complete and rapid absorption of those herbs. It aids in the removal and cleaning of stomach tissue, and is helpful in healing stomach and intestinal ulcers.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR SNORING?

Many attempts to treat snoring have been made through the years without much success. From the standpoint of medications, antihistamines, sedatives, anti-inflammatories, anti-depressives and anti-anxiety preparations have been notably unsuccessful in controlling the problem.

Various types and shapes of pillows have been tried with little success.

Homeopathic medications have a very poor record of success.

Dental appliances that shift the lower jaw forward or pull and hold the tongue forward have only met with limited success.

Finally, the newer surgical procedures using conventional or laser surgery that remove large amounts of tissue from the back of the mouth have proven far less than ideal. They cause pain which may linger for up to 3 months following surgery. Several deaths have now been reported as directly resulting from the procedure. Many complications have also been reported, including the development of nasal speech, difficulty in swallowing, change in taste sensation and nasal regurgitation, due to the removal of large amounts of tissue, occurs when food or liquid that you intend to swallow goes up instead of down, exiting through the nose. The worst problem, however, is that not only does surgery almost never completely eliminate snoring, but when patients having had these surgical procedures were evaluated 13 months after surgery, only 46% even obtained a moderate decrease in snoring!



Snore Formula Eliminates Snoring Naturally.

As heard on radio in the U.S. and Canada with Dennis H. Harris, M.D.

Snore Formula from Snore Formula, Inc., combines both digestive enzymes and natural herbs to relieve annoying snoring symptoms. This highly unique and effective remedy has had over \$12,000,000 in sales over the last three years to satisfied and repeat customers. We offer a 100% satisfaction guarantee or your money back. Click on the link below for complete information.

Eliminate Snoring with Snore Formula!

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*** Notice of Price Change**

Exhibit D

All orders are shipped by the U.S. Postal System. Orders are usually shipped within 48 hours of confirmation and delivery within the U.S. is normally 5 to 7 working days, excluding weekends.

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As heard on radio in the U.S. and Canada with Dennis H. Harris, M.D.

Snore Formula is a unique one of a kind patented remedy with a combination of all natural herbs and digestive enzymes that gently work together to eliminate snoring symptoms and problems.

100% Guaranteed or your money refunded!

Advertised on the radio in the US and Canada featuring Dr. Harris as an authority and guest speaker.

Scott writes...

Let me take this opportunity to thank you for your wonderful product and tell you how much my wife, Diane, and I appreciate the quiet nights we have enjoyed since discovering it. It's very rare when a product actually delivers what it promises but Snore Formula truly does. We have tried most of the other advertised remedies without any satisfaction and I am very pleased to be able to write and say that this product is as close as you can get to an absolute "Miracle".

Beverly writes...

I can't believe how great your product is. I have been using Snore Formula for over 6 months and it has made a world of difference since I have stopped snoring and I really feel better when I wake up. It is well worth the price that you offer. I almost didn't buy it, now I'm glad I did. Thank you Dr Harris!

Complete information on Snore Formula follows below:

A 100% natural product which can markedly reduce or eliminate snoring. This unique combination of digestive enzymes and natural herbs metabolizes excess drainage and shrinks nasal and respiratory membranes, thereby opening air passages to eliminate snoring.

Select and click on a link for information

• **Snore Formula Bibliography**

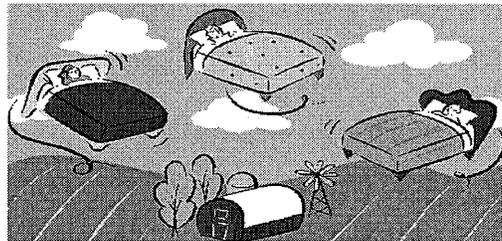
• <u>Dangers of Snoring</u>	• <u>Cause of Snoring</u>
• <u>Social Impact of Snoring</u>	• <u>How Snore Formula Works</u>
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• <u>Testimonials</u>	• <u>Click and Place your Secure Order here</u>

This unique formulation was created by Dennis H. Harris, MD, a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results. *Good Housekeeping* magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users.

Over 160,000 people have used the product over the past 36 months with good to excellent results.

Over 350,000 bottles sold to radio listeners over the last 3 years!

Note: *This formulation is safe for children as long as they can take the tablet. Children age 6 or under, may have difficulty in swallowing the tablet. For children who weigh under 65 pounds it is recommended to give them 1/2 of a tablet.



Sleep quite, peaceful and wake up feeling better!

This is a very unique and effective patented formula that will give you complete satisfaction: Guaranteed!

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Buy Now! Try it tonight!

* Notice of Price Change

The company has received notification from our manufacturer that the prices for raw material and labor has gone up. Due to this increase in labor and material costs we regret that we have to raise our prices on our products. This price increase will be effective on March 1, 2001.

New Prices Effective March 1, 2001

1 60 tablet bottle \$39.95

Buy 2, Get 1 Free! \$79.90

5 bottles = \$99.00 (Internet Special)

12 bottles = \$199.00

With your purchase:

- A 7 page product information brochure and audio cassette tape on Snore Formula is sent with each order
 - In addition, free samples and a 11 page product information brochure on Allergy Formula is sent to you.
-

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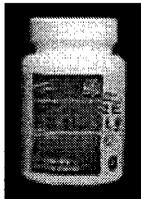


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SNORE FORMULA, INC.

KJ Enterprises

A unique combination of all natural herbs and enzymes that gently work together to prevent snoring. Statistics have proven that over 40% of the population or 100 million people in the United States are chronic, regular snorers!



DANGERS OF SNORING:

- Snorers have a markedly higher risk of developing heart attacks, high blood pressure, or strokes.
- Snorers have a 300% higher risk of becoming involved in an automobile accident.
- Snorers have a 400% to 500% higher risk of daytime fatigue.
- Snoring causes sleep apnea, a serious medical condition, in 20% of all chronic snorers
- 25% of all preadolescent children are chronic snorers, and most of these have some form of sleep apnea, a serious medical condition.
- Snoring causes sleep disturbances that lead to increased anxiety, hyperirritability, decreased memory and poor concentration.

This unique formulation was created by Dennis H. Harris, MD, a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results. *Good Housekeeping* magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users. **Over 150,000 people have used the product over the past 36 months with good results.**

◊ Snore Formula, Inc.	◊ Causes of Snoring
◊ Social Impact of Snoring	◊ How Snore Formula Works
◊ Directions	◊ Ingredients
◊ Testimonials	◊ SECURE ORDER FORM



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SOCIAL IMPACT OF SNORING:

- Snoring often causes resentment between partners, leading to a loss of intimacy and deterioration of relationships.
- Increased irritability leads to failing relationships at home and among co-workers.
- Poor memory and concentration produce decreased work performance.

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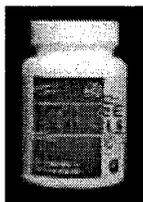


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SNORE FORMULA, INC.

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A unique combination of all natural herbs and enzymes that gently work together to prevent snoring. Statistics have proven that over 40% of the population or 100 million people in the United States are chronic, regular snorers!



DIRECTIONS:

- Take 30 to 40 minutes before bedtime.
- Take by weight as follows:
 - 125 lbs or less, take one tablet.
 - 125-220 lbs, take two tablets.
 - Over 220 lbs, take three tablets.

FAST RESULTS:

Take double the usual dose for the first 3 weeks. When maximum results are obtained, lower the nightly dosage by 1/2 caplet each week to achieve the lowest dose that controls snoring.

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Snore Formula Testimonials

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Snore Formula Testimonials

Product History...

In 1993, Dr. Harris created and began clinically testing a natural oral remedy to eliminate snoring. With more than 86 % good to excellent test results, commercial sales of the product, initially named Snore No More, began in 1995. Sales were undertaken nationally and internationally via direct response radio only. To date, over \$12,000,000 in sales have occurred with more than 300,000 bottles sold. The product was recently renamed Dr. Harris' Original Snore Formula, and is presently marketed nationally through radio direct sales via live shows, 30 and 60 second commercials and 30 minute radio infomercial.

Michael writes...

I am having a good nights sleep finally. I used to wake myself up during the night which was a real bummer as I would not always go back to sleep. Sleeping through the night is great. Thanks a lot.

PS: My girlfriend loves it as much or more than I do.

Ann writes...

My husband uses it for another reason. He has a problem with blocked nasal passages. While he's asleep the passages close, he stops breathing and he wakes up gasping. When he takes Snore Formula his nose stays clearer and he's able to sleep more restfully.

Thank you for a product that helps!

Lonny writes...

The main thing I have noticed is I sleep better. No more multiple wake-ups due to breathing difficulty.

Lee writes...

For years the snoring on the other side of the bed had gotten louder and more often. It had become almost unbearable. With the use of Snore Formula there has been an enormous improvement. What snoring has continued is much, much lighter and much, much softer. There are many, many periods of no snoring at all.

Shirley writes...

I used to snore and snort so loud I would wake myself up. I haven't done that lately. I think one of the best things about taking Snore Formula is the lack of sinus drainage in the morning. I used to hack and spit for the first hour of each day. As my granddaughter, Brittany, tells me it was "gross and disgusting"! She's seven.

Whatever Snore Formula does or however it works, I am grateful that I have discovered it exists. My son-in-law told me about it.

Gregory writes...

In February 1995, I was diagnosed with severe sleep apnea. A CPAP was the suggested treatment for my affliction, but it did not help my condition. I heard your advertisement and ordered a bottle of Snore Formula and my sleep improved immediately. I continue to use it and my sleep has been better than it had been in years. Thanks.

Chloe writes...

The reason I looked into Snore Formula is because my husband used to keep me up at nights with his snoring. So I said I would give it a try and it works! I was so happy. If Snore Formula could work for him it could work for anyone. Thank you very much.

Scott writes...

Let me take this opportunity to thank you for your wonderful product and tell you how much my wife, Diane, and I appreciate the quiet nights we have enjoyed since discovering it. It's very rare when a product actually delivers what it promises but Snore Formula truly does. We have tried most of the other advertised remedies without any satisfaction and I am very pleased to be able to write and say that this product is as close as you can get to an absolute "Miracle".



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SNORE FORMULA, INC.

KJ Enterprises

A unique combination of all natural herbs and enzymes that gently work together to prevent snoring. Statistics have proven that over 40% of the adult population are chronic, regular snorers!



CAUSE OF SNORING:

Most cases of snoring are due to the nightly accumulation of secretions in the back of the throat and the associated tissue swelling. These factors produce a partial airflow obstruction and narrowed airway, allowing vibration of the soft tissues in the throat.

This unique formulation was created by Dennis H. Harris, MD, a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results. *Good Housekeeping* magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users. **Over 150,000 people have used the product over the past 36 months with good results.**

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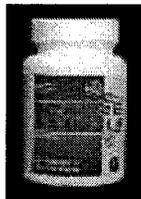


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SNORE FORMULA, INC.

KJ Enterprises

A unique combination of all natural herbs and enzymes that gently work together to prevent snoring. Statistics have proven that over 40% of the adult population are chronic, regular snorers!



HOW SNORE FORMULA WORKS:

The unique combination of natural enzymes metabolizes the secretions, allowing the body to absorb them. The herbs reduce the tissue swelling. The result is to open the airway, smooth out the airflow and eliminate the snoring.

This unique formulation was created by Dennis H. Harris, MD, a recognized medical expert in the field of snoring. Dr. Harris tested this preparation on 220 subjects. Amazingly, 86% of those using this formulation had good to excellent results. *Good Housekeeping* magazine also performed an independent study that demonstrated a marked improvement in the vast majority of users. **Over 150,000 people have used the product over the past 36 months with good results.**

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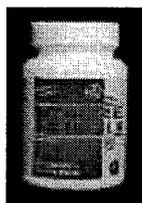


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SNORE FORMULA, INC.

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A unique combination of all natural herbs and enzymes that gently work together to prevent snoring. Statistics have proven that over 40% of the population or 100 million people in the United States are chronic, regular snorers!



INGREDIENTS:

Acerola, Amylase, Cayenne Pepper, Cellulase, Echinacea, Elderberry, Eucalyptus, Fenugreek, Lipase, Protease, Red Clover, Rose Hips, Slippery Elm, Yarrow

HOW SNORE FORMULA WORKS:

The unique combination of natural enzymes metabolizes the secretions, allowing the body to absorb them. The herbs reduce the tissue swelling. The result is to open the airway, smooth out the airflow and eliminate the snoring.

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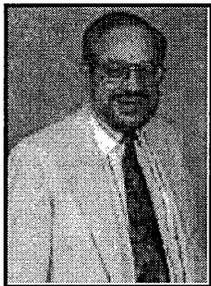
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Dennis H. Harris, M.D.

Biography



Dr. Harris graduated from Ohio State University Medical School in 1963 and completed his internship at Grant Hospital, a University affiliated hospital in Columbus, Ohio in 1964. He then entered a residency training program, specializing in Physical Medicine and Rehabilitation at Ohio State University. Upon completion, he moved to Dallas, Texas in 1966 to become chief resident in a Physical Medicine residency program at Parkland Hospital, Southwestern Medical School, University of Texas. He completed the last year of his residency in 1967 and moved to Scottsdale, Arizona to begin private practice.

In 1968, Dr. Harris established the Department of Physical Medicine and Rehabilitation at Scottsdale Memorial Hospital in Scottsdale, Arizona and was appointed Director of that department which he operated until 1984. Dr. Harris then established the Southwest Pain Control Program and directed that program through 1974. This program was the first chronic pain control program in the Southwest, the eighth program in the country, and the first program to be performed on only an outpatient basis. After the efficacy of the program was well established, the entire program was moved to Mesa Lutheran Hospital in 1974 at the hospital's request. The hospital appointed Dr. Harris as Director of that program, and he maintained this position through 1983.

Dr. Harris subsequently maintained a practice devoted primarily to the non surgical diagnosis and treatment of all conditions of pain. Due to the nature of that practice, many of Dr. Harris's patients were medico legal in nature, having been involved in automobile accidents or work-related accidents. This has enabled Dr. Harris to testify in hundreds of depositions and make countless court appearances as an expert medical witness.

Professionally, Dr. Harris has been continually involved in lecturing and teaching, often lecturing groups of hundreds of physicians or physical therapists. He has presented several papers at national meetings and appeared before large medical audiences during that time.

While in residency at Ohio State University, Dr. Harris became the co-inventor of a gel pad to prevent bed sores, negotiated a licensing agreement with The Stryker Corporation, and subsequently traveled the country, presenting the product at hospital meetings and medical gatherings. During that time, he designed the national sales and marketing program for The Stryker Corporation with regard to that product, and he then trained the national and international sales staff of The Stryker Corporation prior to the introduction of the product.

During the course of his practice, Dr. Harris recognized the benefits of alternative medicine. HarGen Distributing, Inc. was formed to manufacture and distribute natural crystal deodorant products worldwide. Dr. Harris designed, trademarked and patented multiple improvements and new products within the industry.

In 1993, Dr. Harris created and began clinically testing a natural oral remedy to eliminate snoring. With more than 86 % good to excellent test results, commercial sales of the product, initially named Snore No More, began in 1995. Sales were undertaken nationally and internationally via direct response radio only. To date, over \$12,000,000 in sales have occurred with more than 150,000 regular users and over 300,000 bottles sold. The product was recently renamed Dr. Harris' Original Snore Formula, and is presently marketed nationally through radio direct sales via live shows, 30 and 60 second commercials and 30 minute radio informercials.

In 1994, after clarifying the link between snoring, allergies, sinusitis and asthmatic bronchitis, Dr. Harris created and began testing a natural formulation for relief for allergy and sinus symptoms. 83% good to excellent test

results have been obtained. Marketing of this product under the name Dr. Harris' Original Allergy Formula began nationally during the 1st quarter of 1998. Presently, Dr. Harris continues an active research and development program designed to improve the existing products and create new products to effectively help and extend our lives. Dr. Harris has appeared on over 1,500 local and network radio shows and continues to be one of the most popular and sought-after radio guests.



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DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to § 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1.a. Respondent Snore Formula, Inc., is an Arizona corporation with its principal office or place of business at 4105 N. 40th Place, Phoenix, AZ 85018.

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1.b. Respondent Dennis H. Harris, M.D., is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of Snore Formula, Inc.

1.c. Respondent Ronald General is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of Snore Formula, Inc.

1.d. Respondent Gerald L. "Jerry" Harris is an individual also doing business as KJ Enterprises. His principal office or place of business is 3321 Old Mallard Road, Enid, OK 73703.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondents" shall mean Snore Formula, Inc., a corporation, its successors and assigns and its officers; Dennis H. Harris, M.D., individually and as an officer of the corporation; Ronald E. General, individually and as an officer of the corporation; Gerald L. "Jerry" Harris, also doing business as KJ Enterprises, and each of the above's agents, representatives, and employees.

2. "Clearly and prominently" shall mean as follows:

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A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. *Provided, however,* that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.

C. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

3. In the case of advertisements disseminated by means of an interactive electronic medium such as the Internet or other online services, "in close proximity" shall mean on the same Web page and proximate to the triggering representation, and not on other portions of the Web site, accessed or displayed through hyperlinks or other means.

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4. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
5. "Distributor" shall mean any purchaser or other transferee of any product or service covered by this order who acquires such product or service from one or more respondent, with or without valuable consideration, and who sells, or who has sold, such product or service to other sellers or to consumers, including but not limited to individuals, retail stores, or catalog sellers.
6. "Food," "drug," and "device," shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
7. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
8. "Endorsement" shall mean as defined in 16 C.F.R. 255.0(b).

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

- A. Such product or service prevents sleep apnea in adult or child users who would otherwise develop sleep apnea;
- B. Such product or service treats sleep apnea; or

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C. Such product or service eliminates, prevents, or reduces snoring in users of the product or service,

unless at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. *Provided that*, for any representation made by respondent Dennis H. Harris, M.D. as an expert endorser, respondent Dennis H. Harris, M.D. must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise in the form of an examination or testing of the product at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service that has not been shown by competent and reliable scientific evidence to be effective in the treatment of sleep apnea, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the product or service is effective in eliminating, preventing, or reducing snoring, unless they disclose, clearly and prominently, and in close proximity to the representation, that such product or service is not intended to treat sleep apnea; that the symptoms of sleep apnea include loud snoring, frequent episodes of totally obstructed breathing during sleep, and excessive daytime sleepiness; that sleep apnea is a potentially life-threatening condition; and that persons who have symptoms of sleep apnea should consult their physician or a specialist in sleep medicine. *Provided, however*, that for any television commercial or other video advertisement fifteen (15) minutes in length or longer or intended to fill a broadcasting or cablecasting time slot fifteen (15) minutes in length or longer, the disclosure shall be

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made within the first thirty (30) seconds of the advertisement and immediately before each presentation of ordering instructions for the product or service. *Provided further*, that, for the purposes of this provision, the presentation of a telephone number, e-mail address, or mailing address for listeners to contact for further information or to place an order for the product or service shall be deemed a presentation of ordering instructions so as to require the announcement of the disclosure provided herein.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the effect of such food, drug, device, service, or dietary supplement on any disease, or about the effect of such food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of such product or service, unless, at the time the representations are made, respondents possess and rely upon competent and reliable scientific evidence, that substantiates the representation. *Provided that*, for any representation made by respondent Dennis H. Harris, M.D. as an expert endorser, respondent Dennis H. Harris, M.D. must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise in the form of an examination or testing of the product or service at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

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IV.

IT IS FURTHER ORDERED that respondents Snore Formula, Inc., a corporation, its successors and assigns and its officers; Dennis H. Harris, M.D., individually and as an officer of the corporation; Ronald E. General, individually and as an officer of the corporation, and each of the above's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, shall not provide to any person or entity means and instrumentalities that contain any claim about the benefits, performance, efficacy, or safety of any food, drug, device, service, or dietary supplement, unless such claim is true, and substantiated by competent and reliable scientific evidence. For purposes of this Part, "means and instrumentalities" shall mean any information, including but not necessarily limited to any advertising, labeling, or promotional materials, for use by distributors in their marketing or sale of Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement covered under this order, in or affecting commerce.

V.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service in or affecting commerce, shall not misrepresent, in any manner (including but not limited to use of endorsements), expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

VI.

IT IS FURTHER ORDERED that respondents Snore Formula, Inc., a corporation, its successors and assigns and its officers; Dennis H. Harris, M.D., individually and as an officer of the

Decision and Order

corporation; and Ronald E. General, individually and as an officer of the corporation, shall:

- A. Within seven (7) days after service of this order upon respondents, deliver to the Commission a list, in the form of a sworn affidavit, of all distributors who purchased Dr. Harris' Original Snore Formula tablets from respondents or from one of respondents' other distributors on or after January 1, 2001. Such list shall include each distributor's name and address, and, if available, the telephone number and email address of each distributor.
- B. Within thirty (30) days after service of this order upon respondents, send by first class mail, with postage prepaid, an exact copy of the notice attached hereto as Attachment A, showing the date of mailing, to each distributor who purchased Dr. Harris' Original Snore Formula tablets from respondents or from one of respondents' other distributors between January 1, 2001, and the date of service of this order. This mailing shall not include any other document.

VII.

IT IS FURTHER ORDERED that respondents Snore Formula, Inc., a corporation, its successors and assigns and its officers; Dennis H. Harris, M.D., individually and as an officer of the corporation; and Ronald E. General, individually and as an officer of the corporation, shall:

- A. For a period of three (3) years following entry of this order, send a copy of the notice attached hereto (Attachment A) by first class mail, with postage prepaid, to any distributor of Dr. Harris' Original Snore Formula tablets, or any other product or service; *provided, however*, that the requirement of this subpart shall not apply to any distributor who received a copy of the notice attached hereto (Attachment A) pursuant to the requirements of

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subpart VI.B of this order. Such notice shall be sent within one (1) week from the first shipment of respondent's products or programs to said distributor. The mailing shall not include any other documents.

- B. Institute a reasonable program of surveillance adequate to reveal whether any of respondents' distributors are disseminating advertisements or promotional materials that contain any representation about Dr. Harris' Original Snore Formula tablets, or any other product or service manufactured by or purchased from respondent, that is prohibited by Parts I through V of this order.
- C. Terminate all sales of Dr. Harris' Original Snore Formula tablets, or any other food, drug, device, service, or dietary supplement to any distributor who is engaged in disseminating advertisements or promotional materials that contain any representation about Dr. Harris' Original Snore Formula tablets, or any other product or service manufactured by or purchased from one or more respondent, that is prohibited by Parts I through V of this order once respondent knows or should know that the distributor is or has been engaged in such conduct.

VIII.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new medical device application approved by the Food and Drug Administration. Nor shall it prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

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IX.

IT IS FURTHER ORDERED that respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

X.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XI.

IT IS FURTHER ORDERED that respondent Snore Formula, Inc., and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that

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may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XII.

IT IS FURTHER ORDERED that respondents Dennis H. Harris, M.D.; Ronald E. General; and Gerald H. Harris, for a period of ten (10) years after the date of issuance of this order, notify the Commission of the discontinuance of their current business or employment, or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIII.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

Decision and Order

XIV.

This order will terminate on July 24, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Decision and Order

ATTACHMENT A

LETTER SENT TO DISTRIBUTORS WITH WHOM
RESPONDENT HAS DONE BUSINESS BETWEEN
JANUARY 1, 2001,
AND THE DATE OF SERVICE OF THIS ORDER

[To Be Printed on Snore Formula, Inc. letterhead]

[NAME AND ADDRESS OF RECIPIENT]

[DATE]

Dear [DISTRIBUTOR'S NAME]:

This letter is to inform you that Snore Formula, Inc., recently settled a civil dispute with the Federal Trade Commission regarding its advertising for *Dr. Harris' Original Snore Formula* tablets. Among other things, we have agreed to notify distributors of the settlement.

As a result of its agreement with the FTC, Snore Formula, Inc., has consented to desist from, among other practices, making any claims about the effect of any food, drug, device, service, or dietary supplement on any disease, or about the effect of such food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of such product or service, that is not supported by competent and reliable scientific evidence. Competent and reliable scientific evidence is defined as tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. Anecdotal evidence and consumer testimonials are not considered competent and reliable scientific evidence.

Decision and Order

According to the FTC complaint, we did not have a reasonable basis to claim that *Dr. Harris' Original Snore Formula* tablets can prevent sleep apnea in adult and child users of the product who would otherwise develop sleep apnea; can treat the early stages of sleep apnea; or can eliminate, prevent, or significantly reduce snoring; or that scientific testing demonstrates that *Dr. Harris' Original Snore Formula* tablets reduce or eliminate snoring or the sound of snoring for 86% of users.

As always, your responsibility as a distributor is to utilize only claims made directly from corporate communications or to have your advertising approved by the corporation before transmitting it. Failure to comply with these requirements can result in termination.

This letter has been provided for your files. If you have any questions or if you want a copy of the FTC order, please contact [insert name and telephone number of respondents' contact].

Snore Formula, Inc.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from Snore Formula, Inc., its officers Dennis H. Harris, M.D., and Ronald General, and Gerald L. "Jerry" Harris, also doing business as KJ Enterprises ("proposed respondents"). Proposed respondents market "Dr. Harris' Original Snore Formula" tablets, which are advertised to be taken by persons who snore.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

The Commission's complaint charges that proposed respondents failed to have a reasonable basis for claims they made about Dr. Harris' Original Snore Formula tablets' efficacy in (1) preventing sleep apnea in adult and child users of the product who would otherwise develop sleep apnea, (2) treating the "early stages" of sleep apnea, and (3) eliminating, preventing, or significantly reducing snoring. Proposed respondents are also charged with failing to disclose or failing to disclose adequately that persons who have symptoms of sleep apnea should consult a physician because sleep apnea is a potentially life-threatening condition. Proposed respondents are further charged with making false claims that scientific testing establishes that the product can eliminate, prevent, or significantly reduce snoring in 86% of users. The complaint also alleges that Snore Formula, Inc., and its named officers provided the means and instrumentalities to others to disseminate false or deceptive claims about the product. Finally, the complaint alleges that Dr. Dennis H. Harris, M.D., misrepresented, by acting as an expert endorser for the product, that he had exercised his represented expertise in snoring

Analysis

treatment, in the form of an examination or testing of the product at least as extensive as an expert in the field would normally conduct.

Part I of the consent order requires that proposed respondents possess competent and reliable scientific evidence to substantiate representations that Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement prevents sleep apnea in adult or child users who would otherwise develop sleep apnea; treats sleep apnea; or eliminates, prevents, or reduces snoring. It further requires that Dennis H. Harris, M.D., possess and rely upon competent and reliable scientific evidence and an actual exercise of his represented expertise to substantiate representations he makes as an expert endorser.

Part II of the order requires that, for any product or service that has not been shown to be effective in the treatment of sleep apnea, proposed respondents must affirmatively disclose, whenever they represent that a product is effective in eliminating, preventing, or reducing snoring, a warning statement about sleep apnea and the need for consultation with a physician or a specialist in sleep medicine.

Part III of the order requires scientific substantiation for any future claim about the effect of any food, drug, device, service, or dietary supplement on any disease, or about the effect of any food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of any covered product or service. It further requires that Dennis H. Harris, M.D., possess and rely upon competent and reliable scientific evidence and an actual exercise of his represented expertise to substantiate representations he makes as an expert endorser.

Part IV prohibits Snore Formula, Inc., and its named officers from providing to any person or entity "means and instrumentalities" that contain any claim about the benefits, performance, efficacy, or safety of any food, drug, device, service,

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or dietary supplement, unless such claim is true and substantiated by competent and reliable scientific evidence. "Means and instrumentalities" is defined as any information, including but not necessarily limited to any advertising, labeling, or promotional materials, for use by distributors in their marketing or sale of Dr. Harris' Original Snore Formula or any other food, drug, device, service, or dietary supplement covered under the order.

Part V prohibits false claims about scientific support for any product or service.

Part VI requires Snore Formula, Inc., and its named officers to disseminate a notice ("Attachment A") about the order to distributors who have purchased Dr. Harris' Original Snore Formula tablets from respondents or from one of respondents' other distributors on or after January 1, 2001. This notice indicates that Snore Formula, Inc., has agreed to cease making challenged representations, and warns distributors that they may be terminated if they do not conform their representations to the requirements placed on Snore Formula, Inc. Part VII of the order requires dissemination of Attachment A to future distributors, and that Snore Formula, Inc., monitor their distributors, and terminate sales to distributors who make representations prohibited by the order.

The remainder of the proposed order contains standard requirements that proposed respondents maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements of the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the corporation that may affect compliance under the order; notify the Commission of any change in employment by the individual proposed respondents, and file one or more reports detailing their compliance with the order. Part XIV of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

Analysis

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondents. It is not the Commission's intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Commission Opinion

IN THE MATTER OF

POLYGRAM HOLDING, INC., ET AL.OPINION OF THE COMMISSION AND FINAL ORDER IN REGARD TO
ALLEGED VIOLATIONS OF SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket 9298; File No. 0010231**Complaint, July 30, 2001--Opinion and Final Order, July 24, 2003*

In a unanimous Opinion, the Commission addressed actions taken by Respondent PolyGram Holding, Inc. (a predecessor to Vivendi Universal, S.A.) and Warner Communications Inc. – two of the world’s largest music companies – in connection with a joint venture formed in 1997 to distribute audio and video recordings of the 1998 World Cup concert featuring “The Three Tenors,” Jose Carreras, Placido Domingo, and Luciano Pavarotti. The Commission determined that PolyGram and Warner agreed to restrict price discounting and advertising for recordings of the 1990 and 1994 concerts -- before and after the public release of recordings of the 1998 concert -- in violation of Section 5 of the Federal Trade Commission Act. The Final Order, among other things, prohibits the respondents from soliciting, participating in, entering into, attempting to enter into, implementing, attempting to implement, continuing, attempting to continue, or otherwise facilitating or attempting to facilitate any combination, conspiracy, or agreement, either express or implied, with any Seller (as defined by the Order) (A) to fix, raise, or stabilize prices or price levels in connection with the sale in or into the United States of any prerecorded music in any physical, electronic, or other form or format (“Audio Product”) or of any prerecorded visual or audiovisual product in any physical, electronic, or other form or format (“Video Product”), or (B) to prohibit, restrict, regulate, or otherwise place any limitation on any truthful, nondeceptive advertising or promotion in the United States for any Audio Product or any Video Product.

Participants

For the Commission: *Geoffrey M. Green, John Roberti, Cary Zuk, Melissa Westman-Cherry, Geoffrey D. Oliver, and Richard B. Dagen.*

For the Respondents: *Bradley S. Phillips, Glenn D. Pomerantz, and Stephen E. Morrissey, Munger, Tolles & Olsen.*

Commission Opinion

OPINION OF THE COMMISSION

BY MURIS, Chairman, For A Unanimous Commission:

INTRODUCTION

***Nessun Dorma!* – None must sleep!**

This Puccini aria, sung by tenor Luciano Pavarotti in the recording at the heart of our case, announces the edict of the Chinese princess Turandot that no one in Peking may sleep until she solves her problem. The princess has made a bad judgment – agreeing to marry the first suitor who, at peril of death, can answer three riddles. Although this plan once had served her purposes, someone has now answered the riddles, and Turandot is encumbered with a product she neither wants nor can market. She grasps at one last chance to stop the wedding, by guessing the name of the suitor, and will stop at nothing to obtain the information.

Our story takes place not on the opera stage, but in the business world of operatic recordings. The drama is not so stirring, and no one loses his head, at least not literally. The story is troubling, nonetheless. Two recording companies agree to form a joint venture to market a new recording, by three of the world's foremost singers, and to split the costs and profits. By itself, such an agreement, even by competitors, is often beneficial, because it helps bring a new product to market. Here, however, the story turns dark when it becomes apparent that the new recording will repeat much of the repertoire of existing recordings, diminishing its marketing potential and worrying the recording companies. While other businesses might have worked harder to develop an improved or more distinctive product to attract greater consumer interest, our protagonists chose another route. They agreed to restrict their marketing of competing products that they respectively controlled – products that were clearly outside the joint venture they had formed. They imposed a moratorium on discounting and promotion of those recordings that might

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otherwise siphon off sales of the new product. We now consider whether such an agreement unreasonably restrains trade in violation of the antitrust laws. We conclude that it does.

No analytical exercise is more important to U.S. competition policy than defining the bounds of acceptable cooperation between direct rivals. Courts and commentators have written extensively on how Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45, apply to agreements involving competitors.¹ The Federal Trade Commission (“the FTC” or “the Commission”) also has played a formative role in the evolution of horizontal restraints jurisprudence and policy.² Our opinion in this matter

¹ Comprehensive recent treatments of the relevant case law and commentary appear in ABA Antitrust Section, Monograph No. 23, *The Rule of Reason* (1999); VII Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶¶ 1500-12 (2d ed. 2003); *Symposium: The Future Course of the Rule of Reason*, 68 Antitrust L.J. 331 (2000).

² Major FTC contributions to horizontal restraints jurisprudence include *Pacific States Paper Trade Ass’n*, 7 F.T.C. 155 (1923) (condemning agreement by trade associations of paper dealers and their members to adhere to price lists issued by the associations), *enforcement denied in part and granted in part*, 4 F.2d 457 (9th Cir. 1925), *rev’d in part and FTC order enforced*, 273 U.S. 52 (1927); *Virginia Excelsior Mills, Inc.*, 54 F.T.C. 455 (1957) (condemning agreement of excelsior producers to establish common sales agent that set prices for all producers and allocated orders according to relative productive capacity of each producer), *aff’d*, 256 F.2d 538 (4th Cir. 1958); *National Macaroni Manufacturers Ass’n*, 65 F.T.C. 583 (1964) (condemning agreement among pasta producers to fix the inputs used to make their products), *aff’d*, 345 F.2d 421 (7th Cir. 1965); *American Medical Ass’n*, 94 F.T.C. 701 (1979) (condemning AMA’s restrictions on truthful advertising and solicitation by its members), *enforced as*

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provides our first adjudicative opportunity to revisit the issue of competitor collaboration since the Supreme Court's decision in *California Dental Ass'n v. Federal Trade Commission*, 526 U.S. 756 (1999) ("*CDA*"), and the issuance of the Department of Justice and FTC *Collaboration Guidelines*.

modified, 638 F.2d 443 (2d Cir. 1980), *aff'd* by an equally divided Court, 455 U.S. 676 (1982); *Indiana Federation of Dentists*, 101 F.T.C. 57 (1983) (condemning association's efforts to prevent its members from complying with insurers' requests for x-rays with insurance claims), *enforcement denied and order vacated*, 745 F.2d 1124 (7th Cir. 1984), *rev'd and FTC order aff'd*, 476 U.S. 447 (1986); *Superior Court Trial Lawyers Ass'n*, 107 F.T.C. 510 (1986) (condemning boycott designed to help effectuate agreement among attorneys to raise prices), *enforcement denied and remanded*, 856 F. 2d 226 (D.C. Cir. 1988), *rev'd and FTC order aff'd*, 493 U.S. 411 (1990); *Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549, 604 (1988) (condemning restrictions on optometrists' price and non-price advertising); *Detroit Auto Dealers Ass'n, Inc.*, 111 F.T.C. 417 (1989) (condemning agreement among Detroit-area automobile dealers to close dealer showrooms on nights and weekends), *aff'd in part and rev'd in part*, 955 F.2d 457 (6th Cir.), *cert. denied*, 506 U.S. 973 (1992). In addition to developing doctrine through adjudication, the FTC has coauthored guidelines to help build the modern analytical framework for horizontal restraints. See Department of Justice and Federal Trade Commission, *Antitrust Guidelines for Collaborations Among Competitors* (Apr. 7, 2000) ("*Collaboration Guidelines*"); Department of Justice and Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Healthcare* (Aug. 28, 1996); Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995).

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I. BACKGROUND

The Commission issued its complaint in this matter on July 30, 2001. The complaint charges that the Respondents (hereinafter collectively referred to as “PolyGram”) engaged in unfair methods of competition in violation of Section 5 of the FTC Act by agreeing with competitor Warner Communications Inc. (“Warner”) to restrict price competition and forgo advertising.³ The complaint alleges that, after forming a joint venture (whose establishment the Commission does not challenge here) to collaborate in the distribution of audio and video recordings of a concert by the “Three Tenors” at the 1998 FIFA World Cup for soccer in Paris, PolyGram and Warner entered into a side agreement not to discount or advertise their previous Three Tenors products for a period of time preceding and following the release of the new Three Tenors recording. The complaint alleges that these restrictions had the effect of restraining competition unreasonably, increasing prices, and injuring consumers.

A. PolyGram

PolyGram is a group of vertically integrated companies, affiliated with PolyGram N.V., engaged in the business of producing, marketing, and distributing recorded music and videos in the United States and worldwide. In 1998, PolyGram comprised Respondent PolyGram Holding, Inc. (“PolyGram Holding”); The Decca Record Company Limited (“Decca”) (now

³ On July 31, 2001, when the Commission announced the issuance of the complaint against Polygram, it also announced that it had accepted for public comment a consent agreement with Warner, settling similar allegations against Warner. On September 17, 2001, the Commission issued the final consent order against Warner, enjoining agreements with a competitor to fix prices or limit truthful, non-deceptive advertising or promotion for any audio or video product. *Warner Communications Inc.*, Dkt. No. C-4025 (Sept. 17, 2001).

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Respondent Decca Music Group Limited); PolyGram Records, Inc. (“PolyGram Records”) (predecessor of Respondent UMG Recordings, Inc. (“UMG”)); and PolyGram Group Distribution, Inc. (“PGD”) (predecessor of Respondent Universal Music & Video Distribution Corp. (“UMVD”)). IDF 7-11, 23.⁴ In December 1998, the Seagram Company Ltd. (“Seagram”) acquired PolyGram N.V. Seagram combined the music business of PolyGram N.V. (*i.e.*, PolyGram) with its own music business to form Universal Music Group. Two years later, Seagram merged with Vivendi S.A. and Canal Plus S.A. to form Vivendi Universal S.A. (“Vivendi”). Each Respondent is now a subsidiary of Vivendi. IDF 6, 18.

Decca is a music “label” that develops, acquires, and produces recorded music. In 1998, Decca was part of the PolyGram Classics & Jazz (“PolyGram Classics”) label group, a division of PolyGram Records. At all relevant times, Decca owned the copyright to the master recording of the first Three Tenors concert (“3T1”). IDF 14.

PolyGram Classics was the PolyGram operating company responsible for United States sales of classical music produced by PolyGram. PolyGram Classics was responsible for marketing, promoting, pricing, and advertising 3T1 in the United States. IDF 12, 15. PGD provided the distribution and sales force for

⁴ This opinion uses the following abbreviations:

ID - Initial Decision of the Administrative Law Judge (“ALJ”).
IDF - Numbered Findings of Fact in the ALJ’s Initial Decision
CX - Complaint Counsel’s Exhibit
RX - Respondents’ Exhibit
JX - Joint Exhibits
Tr. - Transcript of Trial before the ALJ

We adopt the ALJ’s findings of fact to the extent such findings are not inconsistent with this opinion.

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PolyGram Classics in the United States and executed PolyGram Classics's marketing strategy at the retailer level. IDF 16.

PolyGram Holding is the parent company of Respondents UMG and UMVD, and provides services to its subsidiaries, including legal, financial, business affairs, and human resources services. PolyGram Holding negotiated the collaboration between PolyGram and Warner with regard to the third Three Tenors World Cup concert ("3T3"). IDF 12-13.

B. Warner

Warner was PolyGram's partner in the Three Tenors joint venture. Two Warner entities principally were involved in the conduct at issue here: Atlantic Recording Corp. ("Atlantic"), a Warner label that operates in the United States, and Warner Music International ("WMI"), which manages the music operations of Warner's operating companies outside the United States. IDF 20-22.

C. Factual Background

The Three Tenors are world-renowned opera singers Jose Carreras, Placido Domingo, and Luciano Pavarotti. IDF 4-5. During the 1990s, the Three Tenors released three paired audio and video recordings derived from live concerts at the FIFA World Cup. PolyGram acquired the rights to distribute audio and video recordings of the first performance of the Three Tenors at the Baths of Caracalla in Rome in 1990.⁵ The trio's first album became the best-selling classical record of all time. IDF 27-29. In 1994, the Three Tenors performed a second World Cup concert at Dodger Stadium in Los Angeles. Warner acquired the rights to

⁵ Since 1990, audio and video recordings of 3T1 have been distributed in the United States by PGD and its successor UMVD. PGD was responsible for deciding the wholesale price and advertising strategy for 3T1 in the United States. IDF 17.

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distribute audio and video recordings derived from the second concert (“3T2”). IDF 30, 32. In 1998, the Three Tenors performed a third World Cup concert in Paris. PolyGram and Warner entered into an agreement to collaborate in the distribution of the audio and video recordings of the third concert, with Warner distributing 3T3 in the United States and PolyGram distributing it in the rest of the world. IDF 59-60.

Upon the release of 3T2 in 1994, and until 1998, PolyGram and Warner competed to sell their respective Three Tenors albums. IDF 34. In 1994, Warner launched an expensive and aggressive marketing campaign to support 3T2 in the United States and internationally. IDF 200-09. PolyGram responded to the release of 3T2 by promoting 3T1 aggressively in the United States and other markets, through advertising and price discounts. IDF 210-21. Sales of 3T1 audio and video products in the second half of 1994 increased over 250% compared with sales in the same period in 1993. JX 12. Despite the competition from 3T1, 3T2 was a business success for Warner. IDF 222. During 1996 and 1997, the Three Tenors held concerts in Tokyo, London, Munich, New York, Johannesburg, and Melbourne. PolyGram and Warner competed with each other throughout the world to capitalize on these concerts as an opportunity to drive sales of their Three Tenors products through various promotional activities. IDF 224-31. 3T1 and 3T2 were both among the best-selling classical recordings in the United States in 1994, 1995, 1996, and 1997. IDF 234.⁶

In 1996, PolyGram and Warner each began to negotiate

⁶ In 1994, 3T2 was the no. 2 and 3T1 was the no. 3 best-selling classical album (CX 587); in 1995, 3T2 was no. 1 and 3T1 was no. 5 (CX 588); in 1996, 3T2 was no. 4 and 3T1 was no. 5 (CX 589); and in 1997, 3T1 was no. 9 and 3T2 was no. 12 (CX 590).

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separately with the concert promoter, Tibor Rudas (“Rudas”),⁷ for the rights to distribute the recordings of the next Three Tenors World Cup concert in 1998. PolyGram did not anticipate collaborating with Warner. IDF 54. Initially, Warner planned to distribute 3T3 without a collaboration with PolyGram: its Atlantic label proposed to distribute 3T3 in the United States, with WMI to distribute 3T3 in the rest of the world. IDF 52. The president of WMI, however, decided to pass on the project because he did not think that another Three Tenors album was a good investment. CX 366; Tr. 407-08.

At that time, Pavarotti was under contract to record exclusively for PolyGram’s Decca label.⁸ In 1997, Warner asked Decca to release Pavarotti from his exclusive contract and permit him to record the 1998 World Cup concert for Warner. Instead, PolyGram proposed that Warner and PolyGram work together on the 3T3 project. Warner accepted this proposal. IDF 55-56.

PolyGram and Warner were very concerned that the new Three Tenors album, scheduled for release in August 1998, would not be as original or commercially appealing as the 1990 and 1994 releases. IDF 73. They recognized that the commercial success of 3T3 would depend largely on having a repertoire that was distinct from that of the earlier Three Tenors recordings. IDF 66, 69. In their negotiations with Rudas, PolyGram and Warner sought the right to approve a significant part of the repertoire for the 1998 concert, but Rudas insisted that he and the artists should control

⁷ Rudas is independent of PolyGram and Warner. *See* CX 380.

⁸ Pavarotti was also under contract to record exclusively for Decca at the time of the 1994 3T2 concert. CX 224. In exchange for certain consideration, Decca agreed to waive its rights and allow Pavarotti to record for Warner. IDF 33.

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the choice of songs. IDF 67-68.⁹ PolyGram and Warner ultimately agreed to forgo approval of the repertoire, and the contract with Rudas provided only that Rudas would consider “in good faith” their suggestions as to repertoire. IDF 68, 71-72.

The collaboration between PolyGram and Warner took the following form: In a series of contracts dated October 14, 1997, in return for an \$18 million advance and other consideration, Rudas licensed to Warner the worldwide audio, video, and home television rights to the 1998 concert. IDF 58. Then, in an agreement dated December 17, 1997, Warner licensed to PolyGram the rights to exploit 3T3 outside of the United States, with Warner (through its affiliate Atlantic) retaining the rights to exploit 3T3 within the United States. The contract provided that PolyGram would reimburse Warner for 50% of the \$18 million advance paid to Rudas, and that Warner and PolyGram would share 50-50 the profits and losses from the 3T3 project. IDF 59-60. The contract also provided that Warner and PolyGram would have the right to market a Greatest Hits album and/or a Boxed Set incorporating the 1990, 1994, and 1998 Three Tenors recordings, but the joint venture agreement did not include the marketing rights to the existing 1990 and 1994 Three Tenors albums. JX-10-F; JX 11 at UMG001790 (*in camera*). The contract also contained a limited covenant not to compete, which stated that neither PolyGram nor Warner would release another Three Tenors recording for four years following the release of 3T3, unless such release was pursuant to this agreement. The contract expressly provided, however, that PolyGram and Warner each could continue to exploit its older Three Tenors products. IDF 62-63. Thus, the relationship of 3T1 and 3T2 to the joint venture was clear: ownership and marketing rights for both were outside the joint venture.

⁹ PolyGram also sought to differentiate the 1998 concert by including a guest performer or original songs to be written by Andrew Lloyd Webber, Elton John, Stevie Wonder, or others, but these suggestions were rejected by the Three Tenors. IDF 75-76.

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The operating companies of both PolyGram and Warner began developing marketing campaigns for 3T1 and 3T2 in early 1998. They planned to capitalize on the upcoming Three Tenors concert and the new album as an opportunity to increase sales of their catalog Three Tenor products. IDF 102-05, 115-18.¹⁰ PolyGram and Warner grew concerned, however, that competition from the catalog Three Tenors recordings would reduce the sales of the new Three Tenors album. As a result, they feared that they would not recoup their \$18 million investment. Tr. 485; JX 9-E; JX 94 at 94, 96; JX 100 at 72-73 (*in camera*); JX 102 at 43; CX 202. In March 1998, executives of PolyGram and Warner met and agreed to refrain from advertising or reducing prices of 3T1 or 3T2 audio or video products in all markets in the weeks surrounding the release of 3T3. They called this agreement the “moratorium” agreement. IDF 90-101, 107-13. Warner’s operating companies, however, continued with plans to launch a discounting campaign for 3T2 scheduled to run through December 1998. IDF 118. When PolyGram learned of this, it informed its operating companies that if Warner discounted 3T2, they were free to retaliate with price discounts on 3T1. IDF 119-21, 128, 130. By June 1998, senior management at both PolyGram and Warner believed that the moratorium agreement was likely to fall apart. IDF 126-27, 129, 131-32.

In June 1998, PolyGram and Warner also learned that – contrary to Rudas’s earlier statement that 3T3 would contain an all-new repertoire – the repertoire would substantially overlap with that of the older Three Tenors concerts. IDF 79-81, 133. This unwelcome news added to PolyGram’s and Warner’s concerns that 3T3 would lose sales to 3T1 and 3T2 and would not be commercially successful. IDF 133-36. Later that month, PolyGram and Warner executives exchanged reassurances that the companies would forgo discounting and advertising of 3T1 and 3T2 during the launch of 3T3. IDF 137-44, 147. PolyGram and

¹⁰ “Catalog” is a music industry term that refers to older albums that a record company continues to offer for sale. IDF 93.

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Warner subsequently issued written instructions to their operating companies worldwide that forbade price discounting and advertising of 3T1 and 3T2 from August 1, 1998 through October 15, 1998. IDF 148-53.

In late July 1998, after the Paris concert but before the release of 3T3, the legal departments of PolyGram and Warner learned of the moratorium agreement. IDF 154. The establishment of the moratorium created evident discomfort for PolyGram's attorneys, who raised concerns with PolyGram's management about the moratorium's legitimacy. CX 459; JX 94 at 170-79; RX 719 at 3-7. Shortly thereafter, PolyGram sent a letter to Warner purporting to disavow the existence of a moratorium; likewise, at the request of its counsel, Warner sent a letter to PolyGram purporting to reject the moratorium agreement. IDF 156-57, 160-63. These letters, however, were mere pretense, and the moratorium agreement remained in effect. IDF 158-59, 163-64. The companies complied with the moratorium. Between August 1, 1998 and October 15, 1998, neither PolyGram nor Warner reduced the prices of or funded advertising for its respective catalog Three Tenors products in the United States. IDF 170-76. The companies substantially complied with the moratorium outside the United States, as well. IDF 177-81.

In the end, 3T3 was unsuccessful. Published reviews were generally unfavorable. IDF 167. Several music reviewers noted the overlap in repertoire between the 1998 Three Tenors album and the earlier Three Tenors recordings. IDF 166. Sales of 3T3 fell far short of the companies' projections in 1997, when they thought 3T3 would feature an all-new repertoire, and PolyGram and Warner lost millions of dollars on the project. Tr. 522-25.

In 1999, Decca agreed to waive its exclusive rights to the recording services of Pavarotti to allow him to record a Three Tenors album for Sony. In October 1999, Sony released the album – which consisted of Christmas songs derived from a performance of the Three Tenors in Vienna – with no restriction on marketing activities by PolyGram or Warner in support of their

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catalog Three Tenors albums. IDF 196-99.

D. The ALJ's Initial Decision

After pretrial discovery, ALJ James P. Timony conducted a one-week trial. Complaint Counsel called four live witnesses: Anthony O'Brien, from Atlantic; Rand Hoffman, from PolyGram Holding; Professor Catherine Moore, the director of the Music Business Program at New York University; and Dr. Stephen Stockum, an economist. Respondents called no live witnesses. Both parties introduced deposition testimony and numerous documents. The record closed on March 20, 2002. Following post-trial motions, Judge Timony issued an initial decision and a proposed order on June 20, 2002. Judge Timony's decision ruled that the moratorium agreement constituted an unfair method of competition in violation of Section 5 of the FTC Act.

The ALJ found that the moratorium agreement – created several months after the joint venture agreement between PolyGram and Warner – was not ancillary to the 3T3 joint venture because it was not an integral part of the joint venture or reasonably necessary to market the joint venture product. ID at 50-53. Instead, the ALJ found that the moratorium was a “naked agreement to fix prices and restrict output” that was properly subject to *per se* condemnation. ID at 54, 68.

The ALJ also evaluated the moratorium under an abbreviated (or “quick look”) rule of reason analysis. He ruled that if the moratorium's anticompetitive effects were “obvious,” the burden would shift to Respondents to show the procompetitive benefits of the restraint. ID at 54-55. Turning first to the agreement not to discount 3T1 and 3T2, the ALJ concluded that this arrangement constituted horizontal price fixing, which, as case law has recognized, “threatens the efficient functioning of a market economy.” ID at 56. The ALJ found that PolyGram and Warner previously had competed by reducing the price of 3T1 and 3T2 – to the benefit of consumers – and that such an agreement to forgo discounting had “obvious anticompetitive potential.” ID at 56-57.

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The ALJ also concluded that the agreement to forgo advertising of 3T1 and 3T2 was presumptively anticompetitive. ID at 57. The ALJ explained that economic theory and empirical research showed that advertising restrictions result in higher prices to consumers, and that the evidence here showed that advertising was an important competitive tool used by PolyGram and Warner in marketing the Three Tenors products, creating additional demand and encouraging price discounting. ID at 57-58. The ALJ found that PolyGram and Warner intended that their advertising ban would conceal the better-value Three Tenors recordings so that consumers instead would purchase the higher-margin 3T3 release. Judge Timony concluded that the potential anticompetitive effect of this strategy was “obvious.” ID at 58.

Turning next to Respondents’ efficiency justifications, the ALJ found that the Respondents failed to meet their burden of identifying legitimate procompetitive justifications. ID at 58-65, 68-69. He found that the parties’ principal motive for the moratorium was to shield 3T3 from competition to protect their profits, which he deemed to be an illegitimate justification. ID at 60. He also rejected Respondents’ other proffered justifications, finding that they were implausible and, even if plausible, were invalid because they were unsupported by the evidence in this case. ID at 61-65.

Finally, the ALJ rejected Respondents’ contention that PolyGram withdrew from the moratorium and thus should not be held liable. ID at 65-66.

The ALJ issued a cease and desist order enjoining Respondents for 20 years from again agreeing with a competitor to fix prices or to restrict advertising in connection with the sale of audio and video products, except under certain specified circumstances related to a joint venture.

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E. Questions Raised by the Appeal

Respondents appeal from the ALJ's determination that their conduct violated Section 5 of the FTC Act. They also challenge the appropriateness of the ALJ's cease and desist order. First, Respondents argue that the ALJ erred in concluding that the moratorium is illegal *per se*. They assert that the moratorium falls outside any well-established category of restraints subject to *per se* condemnation. Rather, they contend, the Commission must analyze the moratorium under the rule of reason because the restrictions at issue were reasonably related to the purpose of a legitimate joint venture.

Second, Respondents argue that, in applying the rule of reason, the ALJ erred by relying on a presumption of anticompetitive effects that shifts the burden to Respondents to show plausible procompetitive justifications. Respondents contend that the Supreme Court's decision in *CDA* requires the FTC to offer proof of actual anticompetitive effect before the burden may be shifted to Respondents to justify the restraints.

Third, Respondents argue that, even if the correct legal standard is that restraints categorized as "inherently suspect" warrant a presumption of anticompetitive effects that shifts the burden to a defendant to show procompetitive justifications, the adoption of the moratorium in the context of a procompetitive joint venture dictates that the moratorium not be considered presumptively anticompetitive.

Fourth, Respondents argue that their identification of "plausible" procompetitive justifications requires an assessment of the moratorium's net competitive effects under a full rule of reason analysis.

Fifth, Respondents argue that a cease and desist order is inappropriate here, because there is no basis for concluding that Respondents are likely to engage in similar conduct again.

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II. LEGAL FRAMEWORK

Courts, enforcement agencies, and commentators long have strived to refine operational principles for applying the Sherman Act’s command that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade . . . is declared to be illegal.” 15 U.S.C. § 1. Jurisprudence, commentary, and enforcement experience concerning this prohibition provide the basic foundations for the Commission’s evaluation of horizontal restraints under Section 5 of the FTC Act.¹¹ In this section we identify major aspects of the development of horizontal restraints doctrine and present the framework we will apply to the challenged restrictions in this matter.

A. The Law of Horizontal Restraints

The seemingly categorical language of Section 1 of the Sherman Act mentions none of the analytical concepts – “per se illegality,” “ancillarity,” “quick look,” or “full-blown rule of reason” – that appear in U.S. horizontal restraints jurisprudence. These concepts have evolved under the antitrust common law that Congress contemplated when it cast the nation’s antitrust commands in general terms and entrusted the federal courts and the FTC with developing the operational content for these provisions. Over time, the courts and the FTC have refined that content to account for insights gained from adjudication experience and from developments in economic and legal

¹¹ The Commission’s authority under Section 5 of the FTC Act extends to conduct that violates the Sherman Act. *See, e.g., Federal Trade Commission v. Motion Picture Advertising Serv. Co.*, 344 U.S. 392, 394-95 (1953); *Fashion Originators’ Guild of America, Inc. v. Federal Trade Commission*, 312 U.S. 457, 463-64 (1941). In the case at hand, our analysis under Section 5 is the same as it would be under Section 1 of the Sherman Act.

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learning.¹²

A number of tensions have marked the evolution of horizontal restraints doctrine and the pursuit of techniques for identifying restrictions that suppress competition. Perhaps most important, adjudicatory tribunals have struggled to attain an appropriate balance between achieving accuracy in individual cases, which generally requires fuller inquiry, and streamlining the law's administration, which usually involves making simplifying assumptions and forgoing elaborate analysis when the conduct at issue ordinarily poses grave competitive dangers.

In *Standard Oil Co. v. United States*, 221 U.S. 1 (1911), the Supreme Court made clear that Section 1 establishes a single, general principle governing trade restraints. The "rule of reason" is the touchstone for evaluating challenged conduct.¹³ As stated in

¹² See *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) ("*State Oil*") (noting role of courts in antitrust law "in recognizing and adapting to changed circumstances and the lessons of accumulated experience"); *Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 732 (1988) (use of term "restraint of trade" in Section 1 of Sherman Act "invokes the common law itself, and not merely the static content that the common law had assigned to the term in 1890"); *National Society of Professional Engineers v. United States*, 435 U.S. 679, 688 (1978) (in adopting Sherman Act, Congress "expected the courts to give shape to the statute's broad mandate by drawing on common-law tradition").

¹³ In *Standard Oil*, the Court explained:

[T]he standard of reason . . . was intended to be the measure used for the purpose of determining whether in a given case a particular act had or had not brought about the wrong against which [Sherman Act § 1] provided.

221 U.S. at 60. See also *State Oil*, 522 U.S. at 10 ("Although the Sherman Act, by its terms, prohibits every agreement in 'restraint

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Standard Oil and reiterated later in the same decade in *Chicago Board of Trade v. United States*, 246 U.S. 231 (1918), the purpose of courts in applying the rule of reason is to evaluate the impact of challenged behavior upon competition.¹⁴

In articulating this principle, *Standard Oil* also endorsed a concept that earlier cases such as *United States v. Trans-Missouri Freight Ass'n*, 166 U.S. 290 (1897), and *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899) ("*Addyston Pipe*"), had introduced and that retains vitality today: not all trade restraints require the same degree of fact-gathering and analysis. *Standard Oil*, 221 U.S. at 65. Within the general framework of the rule of reason, certain restraints might be recognized as being so inherently and commonly unreasonable that courts might dispense with an elaborate analysis and condemn them as illegal *per se*. *See id.* (noting that *Trans-Missouri Freight* and other precedent established that the "nature and character" of certain contracts create "a conclusive presumption" that the conduct violates the Sherman Act). Decisions about the appropriate form of inquiry would evolve over time as courts gained experience in evaluating specific business phenomena and accounted for commentary examining the rationale for and effects

of trade,' this Court has long recognized that Congress intended to outlaw only unreasonable restraints.").

¹⁴ In *Chicago Board of Trade*, the Court said:

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.

246 U.S. at 238.

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of various practices.¹⁵

Early decisions also yielded important analytical tools to help courts determine the appropriate form of inquiry for specific restraints. One of the most influential techniques appeared in *Addyston Pipe* in 1898. Seeking to avoid overinclusive application of Section 1, Judge (later Chief Justice) William Howard Taft introduced the concept of ancillarity. *Addyston Pipe*, 85 F. at 281-82. A simple (“naked”) agreement by rivals to set prices, allocate customers, or divide sales territories would be condemned summarily, but the adoption of a uniform pricing schedule as part of the operation of a partnership, which could provide services beyond the capability of any single individual, warranted more tolerant consideration because it was “ancillary” to a legitimate transaction. Even in times when enthusiasm for *per se* rules of liability grew, ancillarity played a crucial role in permitting firms to undertake efficient transactions without Sherman Act condemnation. The willingness of contemporary horizontal restraints jurisprudence to consider efficiency rationales has descended substantially from this ancillarity principle.

Following *Chicago Board of Trade*, particularly from the late 1930s through the early 1970s, the Supreme Court appeared to discern a sharp dichotomy between *per se* and reasonableness analysis – between summary condemnation (in which plaintiffs often prevailed if an agreement was proven) and an abyss of reasonableness analysis (from which defendants routinely

¹⁵ See *State Oil*, 522 U.S. at 21 (“[T]his Court has reconsidered its decisions construing the Sherman Act when the theoretical underpinnings of those decisions are called into serious question.”); see also *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 344 (1982) (“Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.”).

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emerged unscathed).¹⁶ The Court's cases in this era reflected little sense that there were manageable alternatives between the poles. For a time, the acceptance of a dichotomy and the perceived absence of intermediate analytical approaches appear to have helped inspire the Court to categorize an ever wider array of conduct as *per se* illegal. By the early 1970s, the Court had found *per se* condemnation appropriate for a broad range of horizontal arrangements affecting prices,¹⁷ the allocation of customers or

¹⁶ For example, in *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1 (1958) ("*Northern Pacific*"), the Supreme Court explained that "[t]his principle of *per se* unreasonableness . . . avoids the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable – an inquiry so often wholly fruitless when undertaken." *Id.* at 5. The idea that a conventional rule of reason inquiry entailed a vast analytical undertaking took root in the observation of Justice Brandeis in *Chicago Board of Trade* that a court in a rule of reason case

must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be obtained, are all relevant facts.

246 U.S. at 238. This much-quoted formulation is often criticized as too comprehensive and open-ended to be helpful. See VII Areeda & Hovenkamp, *Antitrust Law* ¶ 1502, at 345.

¹⁷ In *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940) ("*Socony*"), the Court endorsed a broad conception of horizontal collaboration that would be deemed to constitute *per se*

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territories,¹⁸ and various concerted refusals to deal.¹⁹ The Court's treatment of vertical restraints exhibited similar trends.²⁰

The inability to recognize intermediate approaches posed difficulties in an important category of cases. In some instances, restraints resembled conduct subject to summary condemnation but also appeared to promote the attainment of valuable efficiencies. While declining to surrender the administrability benefits of *per se* tests, courts searched for ways to distinguish unambiguously harmful restraints from conduct that arguably served legitimate ends. Even early Supreme Court decisions that endorsed a literalist reading of Section 1's ban on "every" contract in restraint of trade disavowed any aim to bar all agreements that in some sense limited the commercial freedom of the parties but

illegal price-fixing. The Court said that "[u]nder the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal *per se*." *Id.* at 223. In a famous footnote, the Court explained that proof of actual anticompetitive effects was not necessary to establish illegality, noting that all price fixing arrangements are "banned because of their actual or potential threat to the central nervous system of the economy." *Id.* at 224 & n. 59.

¹⁸ *United States v. Topco Associates, Inc.*, 405 U.S. 596, 608-10 (1972); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 597-98 (1951).

¹⁹ *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207, 212 (1959).

²⁰ *Albrecht v. Herald Co.*, 390 U.S. 145, 152-54 (1968) (maximum resale price maintenance); *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 379 (1967) (vertical territorial restrictions); *Northern Pacific*, 356 U.S. at 5-6 (tying).

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also generated important efficiencies.²¹ As mentioned above, *Addyston Pipe* injected vital flexibility into Section 1 analysis by introducing ancillarity as a means for sorting benign from pernicious restraints.²²

In the mid- to late 1970s, the Court stepped back from the rigid categorical approach to Section 1 analysis that had prevailed since *Socony*. For horizontal restraints, the pivotal modern case was *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1 (1979) (“*BMI*”).²³ Although the blanket copyright licenses

²¹ See *United States v. Joint Traffic Ass’n*, 171 U.S. 505, 567-68 (1898) (Sherman Act not intended to proscribe all partnerships or the imposition of non-competition covenants to facilitate the sale of good will in a business).

²² See discussion of *Addyston Pipe* at p. 15-16, *supra*.

²³ The Court foreshadowed *BMI* in *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978) (“*Professional Engineers*”). In *Professional Engineers* the Court’s assessment of restraints contained in a professional association’s code of ethics anticipated themes that *BMI* later emphasized. For example, the analysis in *Professional Engineers* resembles the characterization inquiry endorsed in *BMI*. The Court began by noting that the restriction in question “operates as an absolute ban on competitive bidding” and finding that “no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement.” *Id.* at 692. The Court then considered the defendant’s “affirmative defense” that uninhibited competitive bidding “would lead to deceptively low bids, and would thereby tempt individual engineers to do inferior work with consequent risk to public safety and health.” *Id.* at 693. The Court rejected this defense, stating that the possibility that “competition is not entirely conducive to ethical behavior, . . . is not a reason, cognizable under the Sherman Act, for doing away with competition.” *Id.* at 696.

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challenged there were literally agreements to fix prices, the Court recognized that this fact alone did not establish that the practice was “price fixing” subject to the *per se* rule. *Id.* at 8-9. Rather, the Court acknowledged that before a court may condemn collaborative activity as *per se* illegal, it must conduct some assessment of whether the defendant had a legitimate business justification for the collaboration. The Court posed two central questions in attempting to *characterize* the activity: First, is the practice “plainly anticompetitive,” *id.* at 8 (citation omitted), in that it “facially appears to be one that would always or almost always tend to restrict competition and decrease output”? *Id.* at 19-20. And, second, is the practice “designed to increase economic efficiency and render markets more, rather than less, competitive”? *Id.* at 20 (citation omitted).²⁴ *BMI* abandoned the view that posits a sharp dichotomy between rule of reason and *per se* analysis and thus took a major step toward restoring unity to Section 1 analysis.

BMI made explicit and transparent a characterization process that courts performed even during the dichotomy model’s apex. The dichotomy model placed all horizontal restraints in two boxes – one containing *per se* illegal acts and the other containing conduct that warranted a full reasonableness inquiry. To apply this framework in an individual case, the court had to make a threshold decision whether the arrangement at issue belonged in one box or the other. Unless the defendant conceded that its conduct fit exactly within a template of *per se* illegality established in earlier cases, the court was likely to confront arguments that the conduct could not be condemned summarily. To resolve such arguments, courts performed variants of the characterization exercise that *BMI* brought into full view. Under

²⁴ Applying this analysis, the Court concluded that the blanket license was necessary to achieve the efficiencies of integration of sales, monitoring, and enforcement against unauthorized copyright use; thus, a “more discriminating” rule of reason analysis – rather than *per se* condemnation – was required. 441 U.S. at 20-24.

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BMI and its progeny, however, characterization no longer necessarily determines the result of the case.

Five years later, *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984) (“*NCAA*”), reinforced the teaching of *BMI* that courts must engage in an initial assessment of efficiency rationales before condemning conduct as *per se* illegal. In *NCAA*, the Court recognized that the agreements at issue there constituted horizontal price fixing and restrictions on output – categories of practices ordinarily condemned as *per se* illegal. Nonetheless, the Court declined to invoke the *per se* rule. *Id.* at 100-01. The Court noted that some horizontal restraints were “essential” to make the product (college football) available, *id.* at 101-02, and that a joint selling arrangement may have legitimate procompetitive efficiencies. *Id.* at 103 (citing *BMI*, 441 U.S. at 18-23). The Court held that, under these circumstances, a fair evaluation of the competitive character of the restraints at issue required consideration of the *NCAA*’s claimed justifications. *Id.*²⁵

NCAA also established that, even if summary condemnation under the *per se* rule is inappropriate, full rule of reason analysis is not necessarily the alternative. Full rule of reason analysis often entails defining the market and examining market power, inquiries

²⁵ See also *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 295 (1985) (“*Northwest Wholesale Stationers*”) (Court declined to apply *per se* rule to group boycott by a wholesale purchasing cooperative that expelled one of its members, noting that “such cooperative arrangements would seem to be ‘designed to increase economic efficiency and render markets more, rather than less, competitive’” because “[t]he arrangement permits the participating retailers to achieve economies of scale . . . , and also ensures ready access to a stock of goods that might otherwise be unavailable on short notice”) (quoting *BMI*, 441 U.S. at 20).

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that usually require elaborate analysis.²⁶ Sometimes a restraint's competitive harm is evident after an abbreviated rule of reason analysis, obviating elaborate proof under the full rule of reason.²⁷ In *NCAA*, for example, the Court held that "when there is an agreement not to compete in terms of price or output, 'no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement.'" *Id.* at 109 (quoting *Professional Engineers*, 435 U.S. at 692).

Although the Court in *NCAA* went on to consider asserted efficiencies of the association's restrictions, *id.* at 113-17, it did so within the framework of a truncated analysis, without need for a full rule of reason approach. The Court first noted that there was no reason to believe that the restrictions on the product in question

²⁶ When direct evidence of actual effects can be shown, elaborate market definition is unnecessary. *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447, 460-61 (1986); *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) ("an actual adverse effect on competition . . . arguably is more direct evidence of market power than calculations of elusive market share figures"); *Re/Max International, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999) ("an antitrust plaintiff is not required to rely on indirect evidence of a defendant's monopoly power, such as high market share within a defined market, when there is direct evidence that the defendant has actually set prices or excluded competition").

²⁷ See William J. Kolasky, Jr., *Counterpoint: The Department of Justice's "Stepwise" Approach Imposes Too Heavy a Burden on Parties to Horizontal Agreements*, 12 *Antitrust* 41, 44-45 (Spring 1998) (the "quick look" approach "is simply an application of the standard rule of reason analysis in circumstances where the effect on competition is apparent and the defendant's procompetitive explanation for it is facially unconvincing, thus allowing the court to end, *i.e.*, truncate, its analysis").

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(*i.e.*, television rights to college football games) could bring efficiencies to the sale of that product. *Id.* at 113-15. Next, the Court rejected out of hand arguments that restrictions on one product (television rights) could be justified by the prospect of enhancing sales of *another* product (live attendance tickets). *Id.* at 115-17. While noting that this argument, too, lacked a factual underpinning, the Court held that the “more fundamental reason” for rejecting such an argument is that it is “inconsistent with the basic policy of the Sherman Act” to insulate a product from competition in this manner. *Id.* at 116-17. In other words, such an argument is not cognizable as a matter of law.

The *NCAA* Court also made clear that a proffered justification for an otherwise unlawful restraint must be reasonably “tailored” to serve the asserted procompetitive interests. In rejecting the *NCAA*’s arguments that the challenged restrictions could help to preserve competitive balance among amateur teams, the Court emphasized that a variety of less restrictive alternatives were available that would have served that goal at least as well. *Id.* at 119. *See also Collaboration Guidelines, supra* note 2, at § 3.36(b) (“[I]f the participants could have achieved or could achieve similar efficiencies by practical, significantly less restrictive means, then the Agencies conclude that the relevant agreement is not reasonably necessary to their achievement.”); XI Herbert Hovenkamp, *Antitrust Law* ¶ 1913 (1998).

Similarly, in *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447 (1986) (“*IFD*”), the Court did not require extensive market analysis to ascertain the competitive harm resulting from practices that it considered obviously anticompetitive, but instead focused on whether there was an efficiency justification for such practices. There, the Court found that “no elaborate industry analysis is required to demonstrate the anticompetitive nature of” an agreement among dentists to withhold from their customers a desired service (providing x-rays to insurers in conjunction with insurance claim forms); accordingly, “[a]bsent some countervailing procompetitive virtue – such as, for example, the creation of efficiencies in the operation

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of a market or the provision of goods and services, . . . – such an agreement limiting consumer choice by impeding the ‘ordinary give and take of the market place,’ . . . cannot be sustained under the Rule of Reason.” *Id.* at 459 (quoting *Professional Engineers*, 435 U.S. at 692).

Turning to IFD’s justification – that allowing insurance companies to make coverage decisions on the basis of x-rays would harm the quality of care provided to patients – the Court found this argument legally and factually flawed:

The argument is, in essence, that an unrestrained market in which consumers are given access to the information they believe to be relevant to their choices will lead them to make unwise or even dangerous choices. Such an argument amounts to ‘nothing less than a frontal assault on the basic policy of the Sherman Act.’ [*Professional Engineers*, 435 U.S. at 695.] Moreover, there is no particular reason to believe that the provision of information will be more harmful to consumers in the market for dental services than in other markets.

476 U.S. at 463. Because IFD’s justification did not withstand scrutiny, the Court concluded that the challenged practice was unlawful. *Id.* at 465-66.

BMI, *NCAA*, and *IFD* indicated that the evaluation of horizontal restraints takes place along an analytical continuum in which a challenged practice is examined in the detail necessary to understand its competitive effect. Nevertheless, these cases did not provide a clear structure for the required analysis.

In 1988, the Commission itself sought to provide a structured framework in *Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549 (1988) (“*Mass. Board*”):

First, we ask whether the restraint is “inherently suspect.” In other words, is the practice the kind that appears likely,

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absent an efficiency justification, to “restrict competition and decrease output”? . . . If the restraint is not inherently suspect, then the traditional rule of reason, with attendant issues of market definition and power, must be employed. But if it is inherently suspect, we must pose a *second* question: Is there a plausible efficiency justification for the practice? That is, does the practice seem capable of creating or enhancing competition (*e.g.*, by reducing the costs of producing or marketing the product, creating a new product, or improving the operation of the market)? Such an efficiency defense is plausible if it cannot be rejected without extensive factual inquiry. If it is not plausible, then the restraint can be quickly condemned. But if the efficiency justification is plausible, further inquiry – a *third inquiry* – is needed to determine whether the justification is really valid. If it is, it must be assessed under the full balancing test of the rule of reason. But if the justification is, on examination, not valid, then the practice is unreasonable and unlawful under the rule of reason without further inquiry – there are no likely benefits to offset the threat to competition.²⁸

²⁸ 110 F.T.C. at 604 (emphasis in original). The Commission applied the *Mass. Board* framework the following year in *Detroit Auto Dealers Ass’n*, 111 F.T.C. 417, 492-501 (1989), and ruled that an agreement among Detroit automobile dealers to close dealer showrooms on nights and weekends unreasonably restrained trade. The Sixth Circuit rejected the Commission’s conclusion that the restraint was “inherently suspect” as an improper application of the *per se* rule. *Detroit Auto Dealers Ass’n, Inc. v. Federal Trade Commission*, 955 F.2d 457, 470-71 (6th Cir. 1992). In particular, the court criticized the Commission’s reliance on Robert Bork’s argument (in his treatise, *The Antitrust Paradox* (1978)) that there is no economic difference between an agreement to limit shopping hours and an agreement to increase price. 955 F.2d at 470. The Commission’s analysis, however, rested upon more than citations to Judge

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See also VII Areeda & Hovenkamp, *Antitrust Law* ¶ 1511c.

The Commission later retreated from the *Mass. Board* approach in *California Dental Ass'n*, 121 F.T.C. 190 (1996), applying a *per se* rule and the rule of reason as “separate categories” of analysis. *Id.* at 299. The Commission reasoned that the Supreme Court had returned to such a categorical approach in two 1990 cases finding *per se* violations, *Federal Trade Commission v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990) (“SCTLA”), and *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (“Palmer”).²⁹ 121 F.T.C. at 299. Thus, the

Bork’s book. The Commission found ample record evidence demonstrating that showroom hours are an important basis on which dealers compete for customers. For example, it was undisputed that Detroit was the only metropolitan area in the country in which almost all dealers were closed on weekends. 111 F.T.C. at 497-98. Although it disagreed with the Commission’s “inherently suspect” categorization, the court upheld the Commission’s ruling that the limitation of showroom hours was an unreasonable restraint of trade, because hours of operation are a basis of competition among automobile dealers, and because respondents failed to advance valid justifications for the restraint. 955 F. 2d at 471-72.

²⁹ These cases are better understood as being consistent with the view of Sherman Act Section 1 analysis articulated in *NCAA*, *IFD*, and *Mass. Board* – that the court must consider proffered efficiencies before condemning a particular restraint. In *SCTLA*, the Court considered and rejected claimed efficiencies and other justifications before concluding that the challenged conduct (a boycott to force an increase in the compensation of court-appointed counsel) was a naked restraint on price and output falling within the *per se* category. 493 U.S. at 423-24. In *Palmer*, the Court held that an agreement between competitors to divide markets and share revenues was *per se* illegal. The *Palmer* defendants did not argue that the agreement yielded

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Commission held that the dental association's ethical rules restricting price advertising (which precluded, *e.g.*, advertising that characterized a dentist's fees as low or reasonable) were *per se* illegal. *Id.* at 307.³⁰ The Ninth Circuit disagreed with the Commission's *per se* approach and held that the advertising restrictions were properly condemned under an abbreviated rule of reason analysis, because they were facially anticompetitive and because CDA's purported procompetitive justifications, although plausible, lacked evidentiary support. *California Dental Ass'n v. Federal Trade Commission*, 128 F.3d 720 (9th Cir. 1997). While the Supreme Court rejected the Ninth Circuit's analysis as too abbreviated, the Court's opinion leaves no doubt that it views Section 1 analysis as a continuum, rather than a series of distinct boxes (*per se*, quick look, full rule of reason). *California Dental Ass'n v. Federal Trade Commission*, 526 U.S. 756 (1999).³¹

procompetitive efficiencies or a new product. Instead, they tried to avoid liability by contending that the traditional ban on horizontal agreements to allocate sales territories did not apply if a firm agreed with a rival not to enter a market that it previously had not served. In such circumstances, the Supreme Court had little difficulty condemning the agreement outright. 498 U.S. at 49-50.

³⁰ Alternatively, the Commission found the restraints on price advertising illegal under an abbreviated rule of reason analysis. The Commission also found the association's restraints on non-price advertising illegal under an abbreviated rule of reason analysis. 121 F.T.C. at 320-21.

³¹ *CDA* was the first case since *BMI* in which the Court found that the evidence was insufficient to condemn a basic horizontal restraint. In the eleven years following *BMI*, the Court issued six consecutive opinions finding the evidence sufficient to condemn the restraint. *See Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643 (1980) (*per curiam*) ("*Catalano*"); *Maricopa*, 457 U.S. 332; *NCAA*, 468 U.S. 85; *IFD*, 476 U.S. 447; *SCTLA*, 493 U.S. 411; *Palmer*, 498 U.S. 46. In each of these cases, except for *NCAA*, the

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In *CDA*, the Court explicitly acknowledged, for the first time, that its prior cases support an abbreviated or “quick look” rule of reason analysis. *Id.* at 770-71. The Court recognized that advertising restrictions normally harm competition and consumers, but noted that CDA had advanced a number of reasons why its restrictions might nonetheless have served procompetitive purposes in light of the circumstances and context. *Id.* at 773. The restrictions did not ban advertising completely, *id.*, and were designed on their face to avoid false or deceptive advertising and therefore “might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition.” *Id.* at 771. Thus, the Court found that the anticompetitive effect of the restrictions on professional advertising was not obvious. *Id.* at 771, 778. The Court emphasized the professional context of the case before it, questioning whether market forces “normally” found in the commercial world apply to *professional* advertising, especially given that the market at issue was “characterized by striking disparities between the information available to the professional and the patient.” *Id.* at 771-74.³² The Court concluded that, under these circumstances, and in the absence of any empirical evidence supporting the theoretical basis for a presumption of anticompetitive effects, CDA’s identification of plausible procompetitive justifications precluded the “indulgently abbreviated” review of the Ninth Circuit. *Id.* at 774-78.³³

Court reversed the court of appeals. *But see Northwest Wholesale Stationers*, 472 U.S. 284 (Court reversed circuit court’s ruling that wholesale cooperative’s expulsion of member warranted condemnation as *per se* illegal group boycott).

³² The majority opinion used the word “professional” more than 20 times. Respondents’ attempt to downplay the professional setting of *CDA* ignores this striking fact.

³³ Although the Court criticized the Ninth Circuit for prematurely shifting the evidentiary burden to CDA to “adduce hard evidence of the procompetitive nature of its policy,” 526 U.S.

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The Court remanded for a more extended examination of the

at 776, the Supreme Court’s own discussion repeatedly reflects the premise that CDA had identified potential justifications that not only were plausible in theory but also had some grounding in actual experience. *See id.* at 771 (“The restrictions on both discount and nondiscount advertising are, at least on their face, designed to avoid false or deceptive advertising in a market characterized by striking disparities between the information available to the professional and the patient.”); *id.* at 772 (“In a market for professional services, in which advertising is relatively rare and the comparability of service packages not easily established, the difficulty for customers or potential competitors to get and verify information about the price and availability of services magnifies the dangers to competition associated with misleading advertising.”); *id.* at 773 (“The existence of such significant challenges to informed decision making by the customer for professional services immediately suggests that advertising restrictions arguably protecting patients from misleading or irrelevant advertising call for more than cursory treatment as obviously comparable to classic horizontal agreements to limit output or price competition.”); *id.* at 773-74 (“[T]he particular restrictions on professional advertising could have different effects from those ‘normally’ found in the commercial world, even to the point of promoting competition by reducing the occurrence of unverifiable and misleading across-the-board discount advertising.”); *id.* at 774 (“[T]he discipline of specific examples may well be a necessary condition of plausibility for professional claims that for all practical purposes defy comparison shopping.”); *id.* at 775 (“It might be, too, that across-the-board discount advertisements would continue to attract business indefinitely, but might work precisely because they were misleading customers”); *id.* at 778 (the Ninth Circuit “failed to explain why it gave no weight to the countervailing, and at least equally plausible, suggestion that restricting difficult-to-verify claims about quality or patient comfort would have a procompetitive effect by preventing misleading or false claims that distort the market”).

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“tendency of these professional advertising restrictions.” *Id.* at 781. The Court specified that this did not necessarily call for the fullest market analysis. *Id.* at 780. “The truth,” said the Court, “is that our categories of analysis of anticompetitive effect are less fixed than terms like ‘*per se*,’ ‘quick look,’ and ‘rule of reason’ tend to make them appear.” *Id.* at 779. Rather, the Court indicated that rule of reason analysis should be flexible:

As the circumstances here demonstrate, there is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Id. at 780-81.³⁴

CDA stops short of providing a complete analytical framework for the rule of reason inquiry, but gives important guidance about how abbreviated rule of reason analysis is to be conducted. Notably, *CDA* does not require a showing of actual

³⁴ On remand before the Ninth Circuit, the Commission argued that citations in the *CDA* record to a small fraction of the economic evidence relevant to the effects of the advertising restrictions provided an adequate basis to condemn the restraints at issue, and alternatively sought a remand to the FTC to develop a fuller record. The Ninth Circuit concluded that such evidence was not adequate to establish the likelihood of anticompetitive effects in this context, and declined to allow the Commission a “second bite at the apple” by remanding. *California Dental Ass’n v. Federal Trade Commission*, 224 F.3d 942, 950-52, 958 (9th Cir. 2000). In contrast to *CDA*, the record in the instant case contains a full discussion of the relevant economic literature. *See infra* note 52 and accompanying text.

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anticompetitive effects or proof of market power.³⁵ Its principal lesson is that rule of reason analysis must be sensitive to context and distinct characteristics of particular markets, particularly those involving professional services, in evaluating whether general rules of economic theory can be expected to apply. When, as in that case, the defendant articulates plausible reasons why its restrictions may *not* result in competitive harm and may result in cognizable procompetitive benefits, then the plaintiff's showing of likely anticompetitive effects should have an "empirical" foundation, whether based on evidence specific to a particular

³⁵ The Court focused on the restraint itself, identifying "the *likelihood* of anticompetitive effects" as that which must be examined under an abbreviated rule of reason analysis, 526 U.S. at 771 (emphasis added), and thus belied any claim that a showing of actual anticompetitive effect is required. Before each tribunal in *CDA*, including the Supreme Court, the dentists had argued that their restraints could not be condemned without proof that the dentists exercised power in appropriately defined markets. *See, e.g.*, Brief of Petitioner California Dental Association, 28, 42-43 (Nov. 10, 1998). The Supreme Court's *CDA* opinion contains no hint that the error below was failure to conduct a plenary analysis of market power. Indeed, the Court's description of quick look analysis as that by which "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets," 526 U.S. at 770, reveals that proof of market power is not a necessary element of this analysis. *See also* Stephen Calkins, *California Dental Association: Not a Quick Look But Not the Full Monty*, 67 Antitrust L.J. 495, 496 (2000) ("The most important lesson of *CDA* is that the defendant's principal argument throughout the proceeding – that the Commission could prohibit its restraints only through elaborate, formal proof of market power – was rejected.").

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case or in empirical studies of similar markets. *Id.* at 775 n. 12.³⁶ Even in such cases, however, the plaintiff need not necessarily address the full range of issues regarding market conditions, if an “enquiry meet for the case” permits “a confident conclusion about the principal tendency of a restriction.” *Id.* at 781. *CDA* does not preclude – indeed, it is consistent with – the Commission’s approach in *Mass. Board*, and it provides guidance about how that approach should be pursued.

B. Synthesis

As embodied most recently in *CDA* and in our *Collaboration Guidelines*, the development of modern horizontal restraints jurisprudence suggests an analytic framework that proceeds by several identifiable steps. These steps reflect the general principle that antitrust law proscribes only conduct that is likely to harm consumers. In most cases, conduct cannot be adjudged illegal without an analysis of its market context to determine whether those engaged in the conduct or restraint are likely to have sufficient power to harm consumers. In a smaller but significant category of cases, scrutiny of the restraint itself is sufficient to find liability without consideration of market power.³⁷

A plaintiff may avoid full rule of reason analysis, including the pleading and proof of market power, if it demonstrates that the conduct at issue is inherently suspect owing to its likely tendency to suppress competition. Such conduct ordinarily encompasses behavior that past judicial experience and current economic

³⁶ Because the Court relied on literature concerning professions other than dentistry, 526 U.S. at 771-73, the Court presumably would allow evidence concerning analogous professional markets.

³⁷ This synthesis addresses the analytical steps when the plaintiff seeks to avoid pleading and proving market power. It does not address the analysis when market power is at issue.

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learning have shown to warrant summary condemnation. If the plaintiff makes such an initial showing, and the defendant makes no effort to advance any competitive justification for its practices, then the case is at an end and the practices are condemned.

If the challenged restrictions are of a sort that generally pose significant competitive hazards and thus can be called inherently suspect, then the defendant can avoid summary condemnation only by advancing a legitimate justification for those practices. Such justifications may consist of plausible reasons why practices that are competitively suspect as a general matter may not be expected to have adverse consequences in the context of the particular market in question; or they may consist of reasons why the practices are likely to have beneficial effects for consumers.

At this early stage of the analysis, the defendant need only articulate a legitimate justification. *See CDA*, 526 U.S. at 775 & n. 12. While the defendant at this point is not obligated to prove competitive benefits, *id.*, the proffered justifications must be both cognizable under the antitrust laws and at least facially plausible. The first element, cognizability, allows the deciding tribunal to reject proffered justifications that, as a matter of law, are incompatible with the goal of antitrust law to further competition.³⁸ Cognizable justifications ordinarily explain how

³⁸ Although it has earlier roots, the concept of cognizability as a principle limiting the types of justifications has been clearly articulated at least since *Professional Engineers*, where the Supreme Court endorsed the view that certain types of defenses or justifications did not warrant consideration:

We are faced with a contention that a total ban on competitive bidding is necessary because otherwise engineers will be tempted to submit deceptively low bids. Certainly, the problem of professional deception is a proper subject of an ethical canon. But, once again, the equation of competition with deception, like the similar equation with

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specific restrictions enable the defendants to increase output or improve product quality, service, or innovation. By contrast, courts since the earliest decades of the Sherman Act have identified classes of justifications that, because they contradict the procompetition aims of the antitrust laws, will not save restraints from condemnation. For example, a defendant cannot defend restraints of trade on the ground that the prices the conspirators set were reasonable,³⁹ that competition itself is unreasonable or leads

safety hazards, is simply too broad; we may assume that competition is not entirely conducive to ethical behavior, but that is not a reason, cognizable under the Sherman Act, for doing away with competition.

435 U.S. at 696. *See also IFD*, 476 U.S. at 463 (citing *Professional Engineers* in rejecting claim that competition would lead to “dangerous choices” because “there is no particular reason to believe” that consumers cannot digest the information competition provides); *Collaboration Guidelines*, *supra* note 2, at § 3.2 (“Some claims – such as those premised on the notion that competition itself is unreasonable – are insufficient as a matter of law”); compare Thomas G. Krattenmaker, *Per Se Violations in Antitrust Law: Confusing Offenses With Defenses*, 77 *Geo. L.J.* 165 (1988) (cases considered to identify “*per se*” offenses in antitrust analysis are best interpreted as identifying defenses that cannot redeem challenged behavior).

³⁹ *See, e.g., Socony*, 310 U.S. at 224 & n. 59 (“Whatever economic justification particular price-fixing agreements may be thought to have, the law does not permit an inquiry into their reasonableness.”); *United States v. Trenton Potteries Co.*, 273 U.S. 392, 397-98 (1927) (“The reasonable price fixed today may through economic and business changes become the unreasonable price of tomorrow. . . . [I]n the absence of express legislation requiring it, we should hesitate to adopt a construction making the difference between legal and illegal conduct in the field of business relations depend on so uncertain a test as whether prices

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to socially undesirable results,⁴⁰ or that price increases resulting from a trade restraint would attract new entry.⁴¹ Of particular relevance here, the Supreme Court has recognized that a defendant cannot justify curbing access to a more-desired product to induce consumers to purchase larger amounts of a less-desired product. *See NCAA*, 468 U.S. at 116-17. Such justifications are not cognizable and require no further analysis.

The second necessary element of legitimacy is plausibility. To be legitimate, a justification must plausibly create or improve competition. A justification is plausible if it cannot be rejected without extensive factual inquiry. The defendant, however, must do more than merely assert that its purported justification benefits consumers. Although the defendant need not produce detailed evidence at this stage, it must articulate the specific link between the challenged restraint and the purported justification to merit a more searching inquiry into whether the restraint may advance procompetitive goals, even though it facially appears of the type likely to suppress competition.⁴²

are reasonable . . .”).

⁴⁰ *See IFD*, 467 U.S. at 463-64 (confirming that, even in markets for professional services such as dentistry and engineering, there is no reason to believe that informed consumers will make unwise tradeoffs between quality and price); *Professional Engineers*, 435 U.S. at 696 (“[T]he Rule of Reason does not support a defense based on the assumption that competition itself is unreasonable.”).

⁴¹ *See Catalano*, 446 U.S. at 649 (refusing to recognize defense based on argument that limits on credit terms would promote new entry by raising price of product).

⁴² As a practical matter, many of the claimed efficiencies likely will involve claims of “ancillarity.” *See supra* note 22 and accompanying text, *supra* Part II. A (describing development of

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When the defendant advances such cognizable and plausible justifications, the plaintiff must make a more detailed showing that the restraints at issue are indeed likely, in the particular context, to harm competition.⁴³ Such a showing still need not prove actual anticompetitive effects or entail “the fullest market analysis.” *CDA*, 526 U.S. at 779. Depending upon the circumstances of the cases and the degree to which antitrust tribunals have experience with restraints in particular markets, such a showing may or may not require evidence about the particular market at issue, but at a minimum must entail the identification of the theoretical basis for the alleged

ancillarity concept in antitrust analysis as tool for identifying restraints that increase efficiency). Although post-*BMI* cases generally speak of “efficiency,” the ancillary restraints doctrine retains its vitality in evaluating efficiency claims. The concept of ancillarity is implicit in our *Collaboration Guidelines*, see *supra* note 2, which recognize that restraints that otherwise might be considered illegal *per se* warrant more elaborate analysis when they are reasonably related to, and reasonably necessary for the achievement of, procompetitive benefits. *Collaboration Guidelines*, at § 1.2. Moreover, whether or not expressed in terms of ancillarity, the link between defendant’s “plausible” justification and a cognizable benefit must be clear. Unless it leads to a cognizable benefit, a proffered justification is irrelevant to the analysis.

⁴³ Although this stage and the preceding inquiry could be combined, we think it analytically superior and consistent with the relevant case law to first screen the purported justification for legitimacy before engaging in a more extensive, and therefore longer and more resource-intensive, inquiry whether detailed analysis supports or refutes the justification. Antitrust courts have long held that preliminary analysis of purported justifications is appropriate. See, e.g., *supra* Part II.A. (discussing *NCAA* and *IFD*) and notes 38-39 and accompanying text (citing relevant cases).

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anticompetitive effects and a showing that the effects are indeed likely to be anticompetitive. *See id.* at 775 n.12. Such a showing may, for example, be based on a more detailed analysis of economic learning about the likely competitive effects of a particular restraint, in markets with characteristics comparable to the one at issue. The plaintiff may also show that the proffered procompetitive effects could be achieved through means less restrictive of competition. The defendant, of course, can introduce evidence to refute the plaintiff's arguments or to show that detailed evidence supports its proffered justification. Applying a flexible analysis "meet for the case," the tribunal at this stage must ascertain whether it can draw "a confident conclusion about the principal tendency of a restriction" regarding competition. *Id.* at 781.⁴⁴

The plaintiff has the burden of persuasion overall, but not necessarily the burden with respect to each step of this analysis. If the plaintiff satisfies its initial burden of showing that the practices in question are inherently suspect, then the defendant

⁴⁴ In *CDA*, the partial restraints on professional advertising at issue could not be condemned without more evidence than the FTC provided. According to the Supreme Court, the court of appeals failed to test the dentists' proposed justification to determine whether the restraints themselves had "a net procompetitive effect, or possibly no effect at all on competition." 526 U.S. at 771. In terms of the synthesis outlined here, the dentists prevailed either because (1) it was incorrect, without more evidence, to assume that restraints inherently suspect in "normal" (*id.* at 773) markets were similarly suspect in a professional setting, or (2) the restraints at issue had a plausible and cognizable justification that, given the complex nature of professional advertising, could not be rebutted by assumption alone. In either case, the burden on the Commission was the same: it was required to show why the presumption of likely anticompetitive effects that applies in non-professional markets also applied in the professional setting of *CDA*.

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must come forward with a substantial reason why there are offsetting procompetitive benefits. If the defendant articulates a legitimate (*i.e.*, cognizable and plausible) justification, then the plaintiff must address the justification, and provide the tribunal with sufficient evidence to show that anticompetitive effects are in fact likely, before the evidentiary burden shifts to the defendant.⁴⁵ At this stage, the defendant's burden to respond will likely depend in individual cases upon the quality and amount of evidence that the plaintiff has produced to illuminate the competitive dangers of the defendant's conduct.⁴⁶ The defendant also has the burden of producing factual evidence in support of its contentions, including documents within its control.

The existence of a joint venture or other collaboration is simply one circumstance to be considered in assessing the competitive effects of a challenged restraint.⁴⁷ If a joint venture results in

⁴⁵ See, e.g., *IFD*, 476 U.S. at 459 (once plaintiff has met burden of showing likely anticompetitive effects, defendant must show "countervailing procompetitive virtue"); *Law v. National Collegiate Athletic Assn*, 134 F.3d 1010, 1019 (10th Cir.) ("*Law*") (discussing shifting burdens of proof in rule of reason cases), *cert. denied*, 525 U.S. 822 (1998).

⁴⁶ Cf. *United States v. Baker Hughes Inc.*, 908 F.2d 981, 991 (D.C. Cir. 1990) (applying this principle in merger case).

⁴⁷ The DOJ/FTC *Collaboration Guidelines*, *supra* note 2, draw upon the case law discussed above in providing an analytical structure for evaluating joint venture activity. The Agencies' analysis "begins with an examination of the nature of the relevant agreement." *Collaboration Guidelines*, at § 1.2. First, the Agencies ask whether the agreement is potentially *per se* illegal – *i.e.*, is "of a type that always or almost always tends to raise price or reduce output." *Id.* at § 3.2. If the answer is yes, then the Agencies consider proffered justifications. An agreement will escape *per se* challenge if it "is reasonably related to [efficiency-

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competitive benefits, such as the introduction of innovative products or the achievement of production efficiencies, then such benefits are a proper part of the antitrust analysis. But proffered justifications still must be analyzed under the framework stated above, and will entitle the defendant to a fuller review only if they are cognizable and are factually supported to the degree necessary in light of the plaintiff's demonstration of likely anticompetitive effects.

Our intended contribution in this synthesis is to specify more fully the analytical principles that we perceive to be embedded in the case law and our own guidelines and to refine the methodology for applying those principles in practice. Our

enhancing] integration and reasonably necessary to achieve its procompetitive benefits.” *Id.* The *Collaboration Guidelines* explain that before accepting proffered justifications, the Agencies undertake a limited factual inquiry to determine whether claimed justifications that are plausible in theory are plausible in the context of a particular collaboration, and that “[s]ome claims – such as those premised on the notion that competition itself is unreasonable – are insufficient as a matter of law.” *Id.*

Following *CDA*, the *Collaboration Guidelines* specify that rule of reason analysis “entails a flexible inquiry and varies in focus and detail depending on the nature of the agreement and market circumstances.” *Id.* at § 3.3 (citations omitted). The *Collaboration Guidelines* also recognize that full rule of reason analysis may not be required: “[W]here the likelihood of anticompetitive harm is evident from the nature of the agreement, . . . then, absent overriding benefits that could offset the competitive harm, the Agencies challenge such agreements without a detailed market analysis.” *Id.* (citations omitted). The *Collaboration Guidelines* indicate that the underlying issue is the extent to which a challenged restraint in fact likely assists the parties in achieving efficiencies in the market circumstances at issue. *Id.* at § 3.36.

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synthesis thus responds to the need in modern competition policy to devise analytical tests that are sound in substance, transparent in revealing their operational criteria, and administrable in the routine analysis of antitrust disputes.

III. ANALYSIS OF THE CHALLENGED RESTRAINTS

Respondents argue that because the moratorium was “ancillary to a procompetitive joint venture, that agreement cannot be deemed ‘presumptively anticompetitive,’” Respondents’ Opening Brief at 41, and their practices cannot be held illegal without evidence of actual anticompetitive effect. *Id.* at 32. Respondents also argue that their identification of plausible procompetitive justifications means that their practices cannot be held illegal unless the actual, net effect of the restraint is proven to be anticompetitive. *Id.* at 42-44. In terms of the synthesis of horizontal restraints jurisprudence just discussed, Respondents appear to argue that this case falls toward the fuller end of the rule of reason spectrum – if not in fact requiring the fullest, or “plenary,” review. To decide whether Respondents are correct, we first must determine whether the agreement between PolyGram and Warner to forgo discounting and advertising of 3T1 and 3T2 falls within the category of restraints that are likely, absent countervailing procompetitive justifications, to have anticompetitive effects – *i.e.*, to lead to higher prices or reduced output. In making this assessment, we consider what judicial experience and economic learning tell us about the likely competitive effects of such restrictions.⁴⁸

⁴⁸ The Supreme Court has indicated that both sources of insight – the results of case-by-case adjudication and commentary – are relevant as antitrust tribunals form judgments about the competitive significance of observed behavior. *State Oil*, 522 U.S. at 15.

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A. The Likely Anticompetitive Effects of the Moratorium

In keeping with the analytical structure detailed above, we start with an inquiry into whether the restraints at issue here – the agreement not to discount and the agreement not to advertise – are inherently suspect under the antitrust laws, in that they fall within a category of restraints that warrant summary condemnation because of their likely harm to competition. We find ample basis for concluding that they are.

1. The Agreement Not To Discount

The anticompetitive nature of the agreement not to discount is obvious. As the ALJ correctly observed, this is simply a form of price fixing, and is presumptively anticompetitive. *See Catalano*, 446 U.S. at 648 (agreement to terminate the availability of free credit in connection with purchase of good is “tantamount to an agreement to eliminate discounts, and thus falls squarely within the traditional *per se* rule against price fixing”); *NCAA*, 468 U.S. at 100 (horizontal price fixing is “perhaps the paradigm of an unreasonable restraint of trade”).⁴⁹

Antitrust law’s hostility to price fixing is rooted in uncontroversial economic analysis. As Complaint Counsel’s economic expert, Dr. Stockum, testified, an agreement between competitors not to discount is likely to result in higher prices to consumers, restriction of output, and reduced allocative efficiency. Tr. 583-85; JX 104-B. Dr. Stockum therefore concluded that, absent an efficiency justification, the agreement between PolyGram and Warner not to discount their catalog Three Tenors products was very likely to have had anticompetitive effects. Tr. 583-85. Respondents’ own economic expert, Dr. Ordovery, agreed that a naked agreement between competitors to restrict price

⁴⁹ As the Supreme Court said in *Socony*, “the machinery employed by a combination for price fixing is immaterial.” 310 U.S. at 223.

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competition has “clearly pernicious effects on competition and consumers.” RX 716 at ¶ 61.⁵⁰

Moreover, it does not matter that, as Respondents argue, the moratorium applied “only” to two products and “only” for a period of ten weeks.⁵¹ It is patently an elimination of a basic form of rivalry between competitors, and properly triggers an obligation by Respondents to come forward with some showing of countervailing procompetitive justification.

2. The Agreement Not To Advertise

We also find that the agreement between PolyGram and Warner not to advertise their earlier Three Tenors products is presumptively anticompetitive. The Supreme Court in *CDA* indicated that, in ordinary commercial markets – like the one at issue here – complete bans on truthful advertising normally are likely to cause competitive harm. 526 U.S. at 773. Indeed, the Court repeatedly has recognized that advertising facilitates competition. By informing consumers of the nature and prices of the goods or services available in a market, and thus creating an incentive for suppliers of the products and services to compete along these dimensions, advertising “performs an indispensable role in the allocation of resources in a free enterprise system.” *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977); *see also Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 388 (1992). Restrictions on truthful and nondeceptive advertising harm

⁵⁰ Respondents’ expert witnesses did not testify at trial, and thus were not subject to cross-examination. Our references to the statements of Respondents’ experts are to their expert reports and deposition testimony.

⁵¹ As the Supreme Court stated in *Socony*, “the amount of interstate or foreign trade involved is not material . . . , since § 1 of the [Sherman] Act brands as illegal the character of the restraint not the amount of commerce affected.” 310 U.S. at 224 n. 59.

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competition, because they make it more difficult for consumers to discover information about the price and quality of goods or services, thereby reducing competitors' incentives to compete with each other with respect to such features. *See CDA*, 526 U.S. at 773 (“restrictions on the ability to advertise prices normally make it more difficult for consumers to find a lower price and for [suppliers] to compete on the basis of price”); *see also Morales*, 504 U.S. at 388; *Bates*, 433 U.S. at 377-78. These principles apply not just to price advertising, but also to information about qualitative aspects of goods and services. “[A]ll elements of a bargain – quality, service, safety, and durability – and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.” *Professional Engineers*, 435 U.S. at 695.

Complaint Counsel's economic expert testified that an agreement among competitors not to advertise is likely to harm consumers and competition by raising consumers' search costs and reducing sellers' incentives to lower prices. Tr. 587-92; JX 104-C. One reason a restriction on advertising may reduce a seller's incentives to lower prices is that, absent an ability to advertise, lower per-unit prices may not be sufficiently offset by higher volume. Tr. 589-90; JX 105-I ¶ 41; JX 90 at 49-50. Dr. Stockum relied on several empirical studies that have found that advertising restrictions result in consumers' paying higher prices. Tr. 592-600; JX 104-D (citing studies).⁵²

⁵² The studies relied on by Dr. Stockum, as well as other empirical literature concerning the impact of advertising restrictions, are in the record at Appendix A to Complaint Counsel's Findings of Fact, Conclusions of Law, Memorandum of Law in Support Thereof and Order. *See* Lee Benham, *The Effect of Advertising on the Price of Eyeglasses*, 15 J.L. & Econ. 337 (1972) (restricting the advertising of eyeglasses raised the average retail price by \$7.48); Lee Benham & Alexandra Benham, *Regulating Through the Professions: A Perspective on Information Control*, 18 J.L. & Econ. 421 (1975) (prices were 25-

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40% higher in markets with greater professional information controls, including advertising restrictions); Ronald S. Bond et al., *Staff Report on Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry* (Executive Summary), Bureau of Economics, Federal Trade Commission (Sept. 1980) (price for combined eye exam and glasses was \$29 less in cities with least restrictive advertising regimes); John F. Cady, *An Estimate of the Price Effects of Restrictions on Drug Price Advertising*, 14 *Econ. Inquiry* 493 (1976) (states restricting the advertising of prescription drugs have prices that are 2.9% higher than states that do not restrict advertising); Steven R. Cox et al., *Consumer Information and the Pricing of Legal Services*, 30 *J. Indus. Econ.* 305 (1982) (attorneys who advertised had lower fees than those who did not advertise); Roger Feldman & James W. Begun, *The Welfare Cost of Quality Changes Due to Professional Regulation*, 34 *J. Indus. Econ.* 17 (1985) (total loss of consumer welfare from state regulations governing optometrists that, *inter alia*, banned price advertising was \$156 million); Roger Feldman & James W. Begun, *Does Advertising of Prices Reduce the Mean and Variance of Prices?*, 18 *Econ. Inquiry* 487 (1980) (ban on advertising by optometrists and opticians increased prices by 11%); Roger Feldman & James W. Begun, *The Effects of Advertising: Lessons from Optometry*, 13 *J. Hum. Resources* 247 (1978) (price is 16% higher in states that ban optometric and optician price advertising); Amihai Glazer, *Advertising, Information and Prices – A Case Study*, 19 *Econ. Inquiry* 661 (1981) (grocery prices rose because of newspaper strike in Queens County, NY, that eliminated large amounts of supermarket advertising, and fell after the strike ended); Deborah Haas-Wilson, *The Effect of Commercial Practice Restrictions: The Case of Optometry*, 29 *J.L. & Econ.* 165 (1986) (prices were 26-33% lower in markets in which price and non-price media advertising by optometrists occurred); William W. Jacobs et al., *Staff Report on Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising* (Executive

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One of these studies, for example, showed that even a short-lived restraint on advertising can lead to higher prices. Tr. 599-600; IDF 247. On the basis of economic theory and empirical studies, Dr. Stockum concluded that, absent an efficiency justification, Respondents' agreement not to advertise or promote the catalog Three Tenors albums is very likely to be anticompetitive. Tr. 587-92, 616-17; JX 104-D. Dr. Ordovery, Respondents' economic expert, agreed in his deposition that a naked agreement among competitors not to advertise is likely to cause consumer harm. JX 90 at 46-47. This testimony reinforces the general proposition

Summary), Bureau of Economics, Federal Trade Commission (Nov. 1984) (restrictions on attorney advertising resulted in prices that were 5-10% higher); John E. Kwoka, Jr., *Advertising and the Price and Quality of Optometric Services*, 74 Am. Econ. Rev. 211 (Mar. 1984) (prices of eye exams were \$11-\$12 lower in markets with advertising than in markets with advertising restrictions); James H. Love & Frank H. Stephen, *Advertising, Price and Quality in Self-Regulating Professions: A Survey*, 3 Int'l. J. Econ. Bus. 227 (1996) (reviewed 17 studies and found that restrictions on advertising generally have the effect of raising prices paid by consumers); Alex R. Maurizi et al., *Competing for Professional Control: Professional Mix in the Eyeglasses Industry*, 24 J.L. & Econ. 351 (1981) (advertisers charged approximately \$7 less than non-advertisers); Robert H. Porter, *The Impact of Government Policy on the U.S. Cigarette Industry*, in *Empirical Approaches to Consumer Protection Economics* 446 (Pauline M. Ippolito & David T. Scheffman eds., 1986) (demand fell by 7.5% as result of 1971 ban on television and radio advertising in the cigarette industry; during the ban, prices increased from 3-6%); John R. Schroeter et al., *Advertising and Competition in Routine Legal Service Markets: An Empirical Investigation*, 36 J. Indus. Econ. 49 (1987) (advertising made demand more elastic, meaning that consumers were more responsive to price differences); Robert L. Steiner, *Does Advertising Lower Consumer Prices?*, 37 J. Marketing 19 (Oct. 1973) (advertising resulted in lower toy prices to the consumer).

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that restrictions on advertising, such as those imposed here, are likely to reduce competition and harm consumers.

B. Respondents' Justifications

Having concluded that both elements of Respondents' moratorium agreement were indeed inherently suspect restraints of trade because of their likely harm to competition, we turn to Respondents' proffered justifications. Respondents' sole argument in this regard is that the moratorium served a plausible procompetitive interest by preventing the PolyGram and Warner operating companies from using the promotional opportunity created by the 1998 Paris concert and the release of the new album to "free ride" on the joint venture.⁵³ In particular, Respondents assert that PolyGram and Warner were concerned that aggressive promotion of 3T1 or 3T2 during the 3T3 release period would divert sales from 3T3, and that the prospect of such diversion could induce them to withhold promotional efforts in support of 3T3. They further assert that lack of success with 3T3 could have undermined the success of subsequent joint venture products – *i.e.*, a proposed "Greatest Hits" album and a Boxed Set.⁵⁴

⁵³ In contrast to the situation in *CDA*, Respondents here make no argument that the particular industry context renders normal economic conclusions about the competitive impact of price and advertising restrictions inapplicable. This failure is unsurprising, because the present case arises in a conventional *commercial* context, rather than the professional context that so influenced the Supreme Court's approach to *CDA*. See note 32 and accompanying text, *supra*. In any event, as discussed in Part III.C, *infra*, the present record amply shows the likely anticompetitive effects of such restraints in the particular context of the recording industry.

⁵⁴ Respondents also assert, in passing, that the moratorium prevented the PolyGram and Warner operating companies from using "confidential marketing plans developed by the joint venture

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We reject these arguments as a matter of law because they go far beyond the range of justifications that are cognizable under the antitrust laws.⁵⁵ Respondents are not asserting that restraints on the joint venture activities are reasonably necessary to achieve efficiencies in its operations, nor even that expansion of the joint venture is reasonably necessary to achieve such efficiencies. Rather, they are arguing that competitors may agree to restrict competition by products wholly *outside* a joint venture, to increase profits for the products of the joint venture itself. Such a claim is “nothing less than a frontal assault on the basic policy of the Sherman Act,” *Professional Engineers*, 435 U.S. at 695, for it displaces market-based outcomes regarding the mix of products to be offered with collusive determinations that certain new products will be offered under a shield from direct competition.

Preventing free-riding can be a legitimate efficiency. The most widely recognized application in antitrust of this efficiency is, as Respondents suggest, limiting intrabrand competition to improve interbrand competition. *See Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 54-55 (1977). In such cases, the scope of the restraint is necessarily limited to products that are within the control (at least initially) of the entity that owns the restricted brand. Here, despite Respondents’ invocation of a Three Tenors “brand,” there is obviously no such thing, because one entity did not legally control all Three Tenors products. The marketing rights to 3T1 and 3T2 were held not by the joint venture but, rather, independently by the parties to the venture. RX 716 ¶ 31.

partners.” Respondents’ Opening Brief at 44. However, Respondents do not develop this argument further and cite to no record evidence indicating that the moratorium was intended to protect against the misuse of confidential marketing plans.

⁵⁵ Although Respondents state their justification for the moratorium in various ways, their arguments all amount to the same thing: that restraining competition from 3T1 and 3T2 enhanced the marketing of the new joint venture product.

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See supra Part I.C.⁵⁶

Respondents draw our attention to cases in which courts have declined to condemn restrictions that co-venturers have imposed upon each other when the restrictions were justified, at least in part, as reasonable means to control free-riding by the co-venturers. These cases are readily distinguishable from the case at hand. The restraints upheld in the “free-riding” cases Respondents rely upon were limited to the products of the joint venture or other single economic entity involved. For example, in *Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185 (7th Cir. 1985), two retail chains whose offerings were largely complementary, but which were at least potential competitors, agreed to open a new store offering, side by side, the full range of their goods. To protect their respective economic interests and make the new venture possible, they agreed to refrain from carrying competing goods *at that location*. 776 F.2d at 187. The venturers did not agree to restrict competition between their other stores. *Id.*

In *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210 (D.C. Cir. 1986) (“*Rothery*”), *cert. denied*, 479 U.S. 1033 (1987), Atlas, a national van line that contracted with numerous local agent-carriers, altered its previously more flexible arrangement by generally requiring that any moving company doing business as its agent cease interstate carriage on its own account and provide such carriage exclusively in conjunction with Atlas (although competition by wholly independent affiliates was allowed in some circumstances). 792 F.2d at 213, 217. Atlas’s restriction simply required agent-carriers to bring within the

⁵⁶ Had this case involved a merger to create a single entity with rights to market all Three Tenors products, a different analysis would have been required – *i.e.*, one that would weigh potential anticompetitive effects against the prospect of integrative and other efficiencies, under the standards of Section 7 of the Clayton Act, 15 U.S.C. § 18.

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integrated joint venture all of their interstate carriage that used Atlas's equipment, uniforms, services, or other assets of the Atlas network. Because Atlas demonstrated that this restraint was reasonably necessary to eliminate free-riding and thus preserve the efficiencies of the joint venture and because Atlas had only a small percentage of the overall national market, the court upheld the restraints under the rule of reason. *Id.* at 229.

In the present case, however, Respondents and Warner did not bring all of their Three Tenors products into a single, integrated joint venture; indeed, the joint venture agreement expressly provided that PolyGram and Warner could continue to exploit 3T1 and 3T2. JX 10-V. Nor did Respondents and Warner limit the restrictive effects of the moratorium to the product within the joint venture – *i.e.*, 3T3. Rather, they left each of the three Three Tenors products in the hands of an independent economic entity, yet agreed to restrict competition by two of those entities – Respondents with respect to the marketing of 3T1 and Warner with respect to the marketing of 3T2.⁵⁷ Thus, the issue here is whether a joint venture can claim the “efficiency” of limiting “free-riding” from competing products the joint venture neither owns nor otherwise legally controls.

The sort of behavior that Respondents disparage as “free-riding” – *i.e.*, taking advantage of the interest in competing products that promotional efforts for one product may induce – is

⁵⁷ Prior to the moratorium agreement, these independent entities had planned to conduct marketing campaigns for 3T1 and 3T2 during the release of 3T3. IDF 102-05, 115-18. Moreover, Respondents were concerned that it would be difficult for PolyGram and Warner to implement the moratorium consistently on a worldwide basis, because they did not have complete control over the prices for 3T1 and 3T2 charged by their operating companies. IDF 126. Ultimately, however, PolyGram and Warner succeeded in enforcing the moratorium. *See supra* Part I.C.

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an essential part of the process of competition that occurs daily throughout our economy. For example, when General Motors (“GM”) creates a new sport utility vehicle (“SUV”) and promotes it, through price discounts, advertising, or both, other SUVs can “free ride” on the fact that GM’s promotion inevitably stimulates consumer interest, not just in GM’s SUV, but in the SUV category itself.⁵⁸ Our antitrust laws exist to protect this response, because it is in reality the competition that drives a market economy to benefit consumers. There is no doubt that GM’s SUV will likely be more profitable if its competitors do not respond. Promoting profitability, however, is not now, nor has it ever been, recognized as a basis to restrain interbrand competition under the antitrust laws. *See Catalano*, 446 U.S. at 649;⁵⁹ *Law*, 134 F.3d at 1023 (“mere profitability or cost savings have not qualified as a defense under the antitrust laws”); *Chicago Prof’l Sports Ltd. Partnership v. National Basketball Ass’n*, 754 F. Supp. 1336, 1359 (N.D. Ill. 1991), *aff’d*, 961 F.2d 667 (7th Cir. 1992).

⁵⁸ As discussed in Part III.C.3., *infra*, the record reveals that this phenomenon is common in the music industry. JX 91 at 126-27; JX 97 at 46; CX 609 at 71-73, 83-84; CX 610 at 52-54. It is common in many other industries, as well.

⁵⁹ The *Catalano* Court stated:

[I]n any case in which competitors are able to increase the price level or to curtail production by agreement, it could be argued that the agreement has the effect of making the market more attractive to potential new entrants. If that potential justifies horizontal agreements among competitors . . . it would seem to follow that the more successful an agreement is in raising the price level, the safer it is from antitrust attack. Nothing could be more inconsistent with our cases.

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During the oral argument, Respondents in effect conceded this flaw in their argument in their response to a hypothetical positing that Sony had received the rights for 3T3 and then Sony had entered into the same moratorium agreement with Warner and PolyGram restricting price discounting and advertising of 3T1 and 3T2 during the 3T3 release period.⁶⁰ This hypothetical assumes that the same benefits to the Three Tenor “brand” exist that Respondents assert exist in their joint venture. Respondents conceded that for Sony to enter into such an agreement with Warner and PolyGram would be *per se* illegal,⁶¹ even if it might maximize the value of the Three Tenors “brand” in the long term. Transcript of Nov. 4, 2002 Oral Argument at 74-75. Although Respondents claim that the Sony hypothetical is inapposite because the parties here were engaged in a joint venture and own the competitive products, they provided no principled reason why this distinction should make a difference. In each, three products are offered, by three different and independent economic entities. In each, the competitive efforts on behalf of two products are restricted to shield a third product from competition. In each, there is a blatant departure from the principles of free competition on which our antitrust laws are based.

Nor does the fact that the shielded product is a new introduction to the market justify such market manipulation. Suppose, to return to our SUV example, that GM and one of its rivals enter into a joint venture to produce a new SUV, and the parties restrict the competition from their existing, non-joint-

⁶⁰ As mentioned above, *see supra* Part I.C., Sony released a Three Tenors Christmas album in 1999.

⁶¹ The transcript of the oral argument reads “*per se* legal” (Transcript of Nov. 4, 2002 Oral Argument at 74:24), but it is clear from the surrounding discussion of the Sony hypothetical that Respondents’ counsel actually said (or meant) “*per se* illegal.”

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venture SUVs to protect the market for the new SUV.⁶² Any argument that such a stifling of competition is “necessary” to bring the new product to market would face the same fundamental problem that condemns Respondents’ arguments here. Although the antitrust laws favor product innovation, the very concept of a free market is that competitive forces themselves will induce the production of new products that consumers desire and whose availability will enhance consumer welfare. “Antitrust law presumes that competitive markets offer sufficient incentives and resources for innovation, and that cartel pricing leads not to a dedication of newfound wealth to the public good but to complacency and stagnation.” *Freeman v. San Diego Ass’n of Realtors*, 322 F.3d 1133, 1152 (9th Cir. 2003). If a “new” product can succeed in a free marketplace only if it is shielded from competitive forces by a facially anticompetitive agreement between existing competitors, then it is likely no loss to consumers if it is not introduced. To allow such an “efficiency” to justify an agreement between competitors to restrict promotion of competing products is to displace market forces with collusive decisions by competitors regarding what new products consumers

⁶² The Commission’s decision in 1984 to permit General Motors and Toyota to engage in a production joint venture provides an instructive point of comparison. *General Motors Corp.*, 103 F.T.C. 374 (1984). No feature of the GM-Toyota joint venture, either as proposed by the parties or as ultimately approved by the Commission, restricted competition between the two firms concerning existing automobile models that they previously had developed independently. This is a critical distinction between that case and the present one. As a leading commentator noted, “[w]hat excuses the GM-Toyota venture from charges of per se unlawful price fixing is that the venturers did not enter into any agreement to fix the price of their nonventure output.” XI Hovenkamp, *Antitrust Law* ¶ 1908e, at 237-38.

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ought to be offered.⁶³

Indeed, the argument Respondents advance here is remarkably similar to a justification that the *NCAA* Court considered and rejected as antithetical to the antitrust laws. There, addressing the *NCAA*'s argument that restrictions on television broadcasts of

⁶³ Respondents' reliance on Example 10 in Section 3.36(b) of the *Collaboration Guidelines* is misguided. That example addresses the analysis of restrictions imposed by co-venturers in the development of new word processing software products – including, potentially, the cessation of sales of preexisting, competing products. The example makes clear, however, that such restraints may be justified only if they achieve “*cognizable* efficiency goals.” *Id.* (emphasis added). Specifically, the example indicates that such restrictions might be justified if they were necessary for the activities of the joint venture itself, as for monitoring the venturers' contributions of assets or preventing one participant from misappropriating assets the other contributed. The example does not support the notion that a restraint on the marketing of non-venture products can be justified simply because it would increase sales opportunities for the joint venture product. On the contrary, the *Guidelines* make clear that claims “premiered on the notion that competition itself is unreasonable . . . are insufficient as a matter of law.” *Collaboration Guidelines*, at § 3.2. Moreover, as discussed in Example 9 of the *Guidelines*, cost savings from depriving consumers of information useful to their decision making (like the advertising restrictions at issue here) amounts to a service reduction, not a cognizable efficiency.

Further, unlike the joint venture in Example 10, the collaboration at issue here was merely a marketing venture. PolyGram and Warner did not create a novel product. They did not produce the 1998 Three Tenors concert; that was done independently by concert promoter Rudas. Instead, PolyGram and Warner merely collaborated to distribute the audio and video recordings of the 1998 concert. *See supra* Part I.C.

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college football games were necessary to protect live attendance at games, the Court stated:

At bottom the NCAA's position is that ticket sales for most college games are unable to compete in a free market. The television plan protects ticket sales by limiting output – just as any monopolist increases revenues by reducing output. By seeking to insulate live ticket sales from the full spectrum of competition because of its assumption that the product itself is insufficiently attractive to consumers, petitioner forwards a justification that is inconsistent with the basic policy of the Sherman Act.

NCAA, 468 U.S. at 116-17. *See also Professional Engineers*, 435 U.S. at 696 (“[T]he Rule of Reason does not support a defense based on the assumption that competition itself is unreasonable. Such a view of the Rule would create the ‘sea of doubt’ on which Judge Taft refused to embark in *Addyston*, 85 F. at 284, and which this Court has firmly avoided ever since.”).

Another way of analyzing this issue is that the restraints here are not “ancillary” to the production of efficiencies in the sense that Sherman Act cases have employed that concept, even assuming (contrary to our conclusion in Part III.C.3, *infra*) that, as a factual matter, restricting the marketing of 3T1 and 3T2 was reasonably necessary to ensure the vigorous marketing of 3T3. To qualify as an “ancillary” restraint, “an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction,” and it must also “be related to the efficiency sought to be achieved.” *Rothery*, 792 F.2d at 224. A determination of ancillarity includes, of course, the factual inquiry whether a particular restraint was indeed reasonably necessary to permit the parties to achieve a particular efficiency. *See infra* Part III.C.3. But that factual inquiry is not the only pertinent consideration. Suppose, for example, General Motors and Toyota asserted that, to provide incentives for marketing of a new solar-powered car, they would eliminate price promotions on their

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conventional vehicles. Such an argument would be rejected because it is not sufficiently “related to” the efficiency to be furthered.

Cases in which defendants successfully invoked the doctrine of ancillary restraints consistently have involved restraints that affect the joint venture at issue, but not products outside its scope. This was true in both *Rothery* and *Polk Brothers*, as discussed above. Similarly, in *BMI*, the Court upheld the joint setting of prices for the joint venture product (blanket music licenses) because it “accompanie[d] the integration of sales, monitoring, and enforcement against unauthorized copyright use.” 441 U.S. at 20. Significantly, the pricing arrangement approved in *BMI* did not include products outside the joint venture – *i.e.*, licenses on individual compositions – which remained available and were not subject to restraints. *Id.* at 23-24; *see* XI Hovenkamp, *Antitrust Law* ¶ 1908e, at 237-38. Respondents have not cited any cases, nor are we aware of any, in which restraints on the sales of non-joint-venture products have been upheld as “ancillary” to the production of efficiencies by the joint venture itself. On the contrary, the Commission has long recognized that restraints on activities “outside the ambit of the joint venture” cannot be hidden under its cloak. *See Brunswick Corp.*, 94 F.T.C. 1174, 1277 (1979), *aff’d sub nom. Yamaha Motor Co., Ltd. v. Federal Trade Commission*, 657 F.2d 971, 981 (8th Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

In the present case, Respondents and Warner chose to retain control over their respective existing Three Tenors products and to form a joint venture limited to 3T3 and specified follow-on products (*i.e.*, a possible “Greatest Hits” recording and a Boxed Set). They cannot claim the integrative efficiencies that could conceivably have been brought about by combining the production and marketing of all Three Tenors products. Accordingly, the restrictions on the marketing of 3T1 and 3T2 cannot be considered “ancillary” to the present joint venture, *as a matter of law*, because they are not related to the efficiencies the

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joint venture was created to produce.⁶⁴

Thus, we hold that the Respondents' "free-riding" argument is simply an attempt to shield themselves from legitimate interbrand competition. As such, the proffered justification is not cognizable under antitrust law.⁶⁵ This conclusion, together with our previous conclusion that the restraints at issue are of the sort that are likely to harm competition, provides us with ample ground to condemn Respondents' actions as unlawful under Section 1, without further analysis. Arguably, this conclusion could be characterized as a finding of "*per se* illegality" in that we conclude that the restraints at issue are "naked" restraints on competition because they lack a cognizable justification. Yet our mode of analysis, in which we evaluate the proffered justifications at some length and ultimately reject them as not cognizable in an antitrust analysis, closely tracks that of the Supreme Court in *Professional Engineers* and *NCAA* – both cases that the Court described as applying the rule of reason.⁶⁶ In the end, the label matters less than the substance of

⁶⁴ As discussed in Part III.C.3, *infra*, the restraints on the marketing of 3T1 and 3T2 also fail to qualify as ancillary *as a matter of fact*, in that the record shows that such restrictions were not actually necessary to ensure the introduction and vigorous promotion of 3T3 and any covered follow-on products.

⁶⁵ Accordingly, we have no need to determine whether Respondents' proffered justification is "plausible" in a purely factual sense. Because it is not cognizable under antitrust law, it has no relevance to our analysis. *See* note 42, *supra*. In any event, as we determine in Part III.C.3, *infra*, Respondents' attempted defense also fails factually.

⁶⁶ *See* discussion of *NCAA*, at p. 19-21, *supra*; *see also Professional Engineers*, 435 US at 688 ("to evaluate this argument it is necessary to identify the contours of the Rule of Reason and to discuss its application to the kind of justification asserted by petitioner") and at 435 U.S. at 695 ("It is this restraint

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the analysis, the purpose of which remains “to form a judgment about the competitive significance of the restraint.” *Professional Engineers*, 435 U.S. at 692. Here, we have no doubt that the restraints before us harm competition and must be condemned.

C. A More Detailed Factual Analysis

Our analysis could properly end at this point. Respondents’ only proffered justification is not cognizable as a matter of law, and therefore triggers no need to go beyond the analysis presented above. Even if we concluded, however, that Respondents had offered a cognizable and plausible justification and that a more elaborate analysis were therefore needed, analysis of the facts here would only reconfirm our ultimate conclusion. The extensive factual record regarding practices in the recording industry and Respondents’ own prior course of conduct establishes that the harm to competition not only is inferable from the nature of the conduct but is established as a matter of fact. And the record likewise shows that Respondents’ proffered justification regarding free riding and the supposed need to ensure the vigorous promotion of 3T3 would fail as a factual matter, even if it were legally cognizable.

that must be justified under the Rule of Reason . . .”). Of course, even this type of analysis is unnecessary in cases with no possible arguments that restraints are needed to achieve beneficial results, and a more traditional *per se* approach remains appropriate. *See, e.g., United States v. Andreas*, 39 F. Supp. 2d 1048, 1058-61 (N.D. Ill. 1998) (rejecting arguments that rule of reason can apply to criminal case charging price fixing and volume allocation imposed to restrict output), *aff’d*, 216 F.3d 645, 666-68 (7th Cir. 2000). Such matters are commonly the subject of criminal prosecution and are appropriately deemed *per se* illegal, as are other restraints for which the proffered justifications can likewise be dismissed summarily. *See also Palmer*, 498 U.S. at 49-50; *SCTLA*, 493 U.S. at 424; *Catalano*, 446 U.S. at 649-50.

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1. Competitive Effect of Respondents' Discounting Restrictions

The record evidence shows that the moratorium's price restraint not only was inherently suspect, but also actually harmed competition and consumers. In the sale of recorded music, as in other industries, price discounting is an important dimension of competition. IDF 238-42. Executives from PolyGram and Warner testified that their companies commonly offer price discounts to retailers, on catalog products as well as new releases, and that such discounts increase sales. IDF 239. PolyGram and Warner also commonly provide retailers with cooperative advertising funds, which function as a discount from the wholesale price.⁶⁷ IDF 217-18; CX 603-Z-18 (*in camera*). These wholesale discounts encourage retailers to sell the product to consumers at reduced retail prices. IDF 220; JX 100 at 91-92 (*in camera*).

⁶⁷ Cooperative advertising is a monetary commitment that the record label makes to retailers to support both out-of-store advertising (*e.g.*, print, radio, and television advertising) and in-store promotion (*e.g.*, posters and floor displays). Out-of-store advertising is intended to draw customers into the store by informing them where a recording may be purchased and at what price. In-store advertising is designed to increase the likelihood that, once inside the store, the consumer buys a specific recording. JX 105-F; Tr. 48-54, 58-60, 194-96. When PolyGram provides cooperative advertising funds, the retailer provides the advertising and then deducts the value of the cooperative advertising from the amount it pays for the product it purchases from PolyGram. Cooperative advertising thus functions as a price discount. IDF 217-18. Indeed, industry participants recognize that cooperative advertising funds are a form of discount, because they represent the partial assumption by the recording company of expenses that retailers would otherwise bear. *See* CX 603-P (*in camera*) (discussion by Warner of cooperative advertising).

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Prior to the moratorium, Respondents discounted prices as part of the marketing strategy for their respective Three Tenors products. In 1994, PolyGram responded to the release of 3T2 by launching an aggressive marketing campaign for 3T1 worldwide, with price discounting in many markets. JX 29 (“PolyGram were able to sell an additional one million copies of their 1990 album on the back of our new record in 1994. This was achieved through aggressive TV advertising, print advertising, extensive rack exposure of their record at retail *and a price reduction.*”) (emphasis added); JX 12 (in the U.S., 3T1 audio sales in 1994 increased 274% over 1993 sales as a result of marketing campaign); IDF 214-21. In the United States, for example, PolyGram provided cooperative advertising funds to retailers to increase sales and encourage lower retail prices for 3T1. IDF 219-20. In 1996 and 1997, during the Three Tenors’ world concert tours, PolyGram again offered 3T1 at a discounted price in many markets. IDF 224-25, 241; CX 299 at 3TEN00005903 (“You can be certain Decca will be planning to exploit this concert tour with pricing campaigns . . .”). In early 1998, many PolyGram and Warner operating companies planned to reduce the price of 3T1 and 3T2 as part of aggressive marketing campaigns, including promotional activities planned for the weeks surrounding the release of 3T3. IDF 102-05, 115-18. As a result of the moratorium agreement, however, 3T1 and 3T2 ultimately were sold only at full price during the release of 3T3. IDF 170-81.

Respondents argue there is no evidence that the pricing (or advertising) of 3T1 or 3T2 in the United States would have been different without the moratorium. In particular, Respondents assert that in 1994 PolyGram did not discount 3T1 in the United States, and that evidence cited by the ALJ regarding PolyGram’s and Warner’s plans in 1998 to discount 3T1 and 3T2 related solely to operating companies outside of the United States. Respondents’ Opening Brief at 16-17. Respondents appear, however, to hold an artificially narrow view of what constitutes price discounting. Although one method of price discounting, called a “mid-price campaign,” is not used in the United States, Tr. 184-86, the evidence shows that record companies in the

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United States – including PolyGram and Warner – routinely use other forms of price discounting, such as wholesale discounts offered to retailers on new releases or restocking campaigns for catalog products. JX 100 at 91-92 (*in camera*); CX 609 at 49-50; Tr. 44-45. Record companies in the United States – again, including PolyGram and Warner – also use cooperative advertising to achieve what is effectively a discount in the wholesale price, without actually lowering the suggested list price. Tr. 66-68, 187, 808; IDF 217-18, 220.⁶⁸ Moreover, the moratorium applied worldwide, not merely to foreign markets. As Dr. Stockum explained, when direct competitors form an agreement not to discount, “it is a safe economic inference to draw that they intend to stop discounting that would otherwise have occurred.” JX 85 at 45-46. This inference is particularly safe where it appears that the parties’ counsel cautioned them about the legal risks of a moratorium on discounts. *See* p. 9, *supra*.

On this record, we find that the agreement by PolyGram and Warner not to discount 3T1 and 3T2 in the period surrounding the release of 3T3 not only is presumptively anticompetitive, but also eliminated actual price discounting that had occurred previously in the industry, including competition between 3T1 and 3T2 upon the release of 3T2.

2. Competitive Effect of Respondents’ Advertising Restrictions

Here, in contrast to *CDA*, Respondents made no effort to articulate any reason why the market in question (the sale of

⁶⁸ The evidence is clear that PolyGram employed cooperative advertising for 3T1 in 1994 in the United States. For example, in September 1994 – the first full month after the release of 3T2 – PolyGram returned to retailers through 3T1 cooperative advertising programs approximately 9% of the money generated from 3T1 sales. IDF 219.

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recorded music) falls outside the “general rule” that advertising restrictions tend to have anticompetitive effects. *See* 526 U.S. at 771. Nevertheless, the record evidence confirms that such principles indeed apply fully to the recorded music industry, and that the advertising restrictions imposed here were harmful to competition. *See* Tr. 601-03. The record shows that advertising is an important basis of competition in this industry. JX 105-F-G. Record companies spend considerable sums of money advertising their products. CX 609 at 57-59; JX 101 at 12-13. Such advertising serves to inform consumers about the availability of alternatives, sales locations, prices, and quality differences among competing products. Tr. 53-54, 58-59, 62-64. Complaint Counsel’s music industry marketing expert, Dr. Moore, explained that a record company’s decisions regarding advertising and wholesale price are linked, and if there is no advertising, there is less incentive for the company to offer the recording at a significantly reduced price. JX 105-I ¶ 41. Dr. Moore further testified – and Respondents’ executives confirmed – that record companies advertise to increase their sales, and that such advertising generally results in lower retail prices for consumers. Tr. 58-59, 64-67; JX 87 at 79-80, 90; CX 609 at 59; CX 610 at 50.

Furthermore, before the moratorium, advertising was an important part of competition between 3T1 and 3T2. In 1994, when 3T2 was released, PolyGram advertised to inform consumers that 3T1 was the “original” Three Tenors recording, was still widely available, and indeed was often available at a discounted price. IDF 210-20. Largely as a result of its marketing campaign, PolyGram sold almost one million audio and video recordings of 3T1 in the second half of 1994, as compared with 377,000 in the same period in 1993. JX 12. In turn, Warner used advertising to create a distinct identity for 3T2, suggesting to consumers that the newer release was the superior product. IDF 201-09.⁶⁹ PolyGram and Warner again used advertising to

⁶⁹ For example, Warner’s 1994 marketing plan for 3T2 stated:

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highlight the advantages of their respective Three Tenors products during the Three Tenors' world concert tours in 1996 and 1997. IDF 224-34.

In 1998, PolyGram and Warner operating companies began to plan advertising campaigns for their respective catalog Three Tenors products in connection with the upcoming Paris concert. IDF 102-03, 105, 115-18, 255-58. PolyGram and Warner subsequently instructed their operating companies that, because of the moratorium agreement, advertising of 3T1 and 3T2 had to end before 3T3 was released. IDF 107, 147-49. The ban on advertising was intended to protect sales of 3T3 by withholding information from consumers about the nature and price of competing products. As one Warner executive explained at trial, the companies did not want consumers to "start comparing the repertoire along with the price and make a determination that, you know, the '94 concert is just fine for a few dollars less." Tr. 487. We agree with the ALJ that the anticompetitive effect of this strategy is obvious. IDF 224-34.

3. Inadequacy of Respondents' Free-Rider Defense

The foregoing analysis shows that the price and advertising restrictions Respondents imposed were inherently suspect as a matter of economic theory and also were demonstrably anticompetitive in the particular industry context in which they were imposed. Although we have found it unnecessary to engage in "the fullest market analysis," *CDA*, 526 U.S. at 779, we have

In order to counter the perceived threat of competitive imitation products which will aim to satisfy demand in the period directly around the concert using similar repertoire and perceptually identical artists, the concept of the genuine or "real thing" will underpin all local implementation of the [marketing strategy].

CX 259 at 3TEN00011109.

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examined evidence of industry practice and the past practices of the very participants in the present scheme, as well as the consistent economic literature regarding the likely effects of such practices. By any standard, this is an enquiry “meet for the case,” allowing us to arrive at a “confident conclusion” about the anticompetitive nature of these restraints. *Id.* at 781. An antitrust defendant can avoid liability in these circumstances only by making a concrete showing of “countervailing procompetitive virtue.” *See IFD*, 476 U.S. at 459. Respondents have failed to make such a showing.

As discussed above, Respondents’ only proffered justification is impermissible as a matter of law, because the supposed “efficiency” of restraining competition in the offering of products outside of a joint venture to enhance market opportunities for a new joint venture product is not cognizable under the antitrust laws. Nevertheless, in this section we examine the record evidence on these restraints and conclude that, *even if* Respondents could properly defend on the basis that restricting the marketing of 3T1 and 3T2 was reasonably necessary to ensure the vigorous marketing of 3T3, the record simply does not support that argument as a factual matter.

The joint venture unquestionably would have proceeded and the new product would have been brought to market without the moratorium. Initially, Warner planned to market and distribute 3T3 on its own, without any collaboration from PolyGram. IDF 52. Furthermore, PolyGram and Warner were contractually committed to the formation of the joint venture and the creation of 3T3 months before discussions of the moratorium began. IDF 263. Although the timing of the moratorium is not dispositive, it is certainly relevant to an assessment of whether the moratorium was reasonably necessary to achieve the procompetitive benefits of the collaboration. At trial, a Warner executive testified that even if PolyGram and Warner had not agreed to the moratorium, Warner was committed to distribute 3T3 in the United States. Tr. 446-47. Moreover, the fact that the joint venture agreement itself expressly contemplated that PolyGram and Warner would remain

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free to exploit the earlier Three Tenors albums strongly suggests that the parties did not view a ban on competition from these products as important to the efficient operation of the joint venture. JX-10-J-K.

The evidence in this case shows that the prospect that PolyGram and Warner operating companies would discount and advertise 3T1 and 3T2 during the 3T3 release period did not diminish Warner's incentives to promote 3T3 in the United States. Respondents' marketing expert, Dr. Wind, acknowledged in his deposition that firms commonly capitalize on the promotional activities of their competitors, and sellers generally respond to this challenge by using advertising and other marketing tools to create a distinct identity for the target product. JX 91 at 125-29, 133-34; IDF 277-79. In particular, within the recorded music industry, the diversion of sales identified by Respondents is commonplace, and advertising intended to benefit one album often leads to sales of competing albums, including catalog albums by the same artist. IDF 280; Tr. 87-88, 264-65; JX 89 at 33-35; JX 87 at 69-72; JX 101 at 183-84; JX 102 at 114-15; JX 609 at 71-73. As the president of WMI wrote when informed that the moratorium agreement would prevent his operating companies from implementing their plans to promote and discount 3T2 when 3T3 was released:

There is nothing sinister nor underhanded in marketing catalog on the back of a significant related event or new release. In fact, as you well know, this is the normal and traditional practice of our industry.

JX 8.⁷⁰

⁷⁰ In economic terms, one reason for this practice is that, for certain consumers, prior recordings are apparently complements, not substitutes. That is, for these consumers a new recording can increase the attractiveness of previous recordings.

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Complaint Counsel's music industry marketing expert testified, and the parties' executives confirmed, that the prospect of a new album's losing sales to competing catalog products typically does not lead record companies to curtail their marketing of a new album. Tr. 88-90; JX 105-H; CX 610 at 54-55; CX 609 at 71-80, 85-86. For example, when Warner released 3T2 in 1994, it anticipated that PolyGram would take advantage of the promotional opportunity arising from the release of 3T2 to advertise and discount 3T1. IDF 202. But Warner did not cut back on its marketing of 3T2. To the contrary, it launched an aggressive and expensive international marketing campaign in support of 3T2, competing by creating a distinct identity for 3T2. Tr. 89-98; IDF 201, 203-09.

The evidence here shows that marketing activities in support of 3T3 would not have been curtailed on account of the promotion of 3T1 and 3T2. IDF 288-91. Witnesses representing both Warner and PolyGram testified that 3T3 would have been appropriately promoted without the moratorium, and that the moratorium had no effect on the resources for advertising and promoting 3T3. Tr. 490; JX 94 at 87-89; JX 95 at 89-90; JX 101 at 85-86; IDF 288-91. Indeed, in June 1998, when it appeared that the moratorium would fall apart, PolyGram did not alter its marketing strategy or cut back on its advertising budget. IDF 129.

Respondents fail to point to any convincing countervailing evidence that "opportunistic" behavior by PolyGram and Warner operating companies would have led Warner to reduce its level of marketing of 3T3 in the United States. Even Respondents' economic expert, Dr. Ordover, was unable to conclude that promotion of 3T1 and 3T2 was a significant concern in the United States; rather, he found that the moratorium was motivated by concerns about promotion of 3T1 and 3T2 in Europe. JX 90 at 36-37; IDF 294-96. Even if the evidence supported a conclusion that promotional activities by the operating companies in Europe were a concern, this would not justify a ban on discounting and advertising in the United States. *See Rothery*, 792 F.2d at 224 ("If [a restraint] is so broad that part of the restraint suppresses

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competition without creating efficiency, the restraint is, to that extent, not ancillary.”). Moreover, although Dr. Ordoover opined that the moratorium was “reasonably necessary” to avoid free-riding, he defined “reasonably necessary” as meaning not obviously pretextual. IDF 297-98. This meaning of “reasonably necessary” is contrary to the case law. *See Rothery*, 792 F.2d at 224 (restraint “must be subordinate and collateral to a separate, legal transaction” *and* “related to the efficiency sought to be achieved”). Dr. Wind, Respondents’ marketing expert, opined that the moratorium plausibly benefitted consumers because it provided incentives for PolyGram and Warner to produce 3T3 and invest in promoting the album, but he could not identify any record evidence that supported his opinion. JX 91 at 111-15, 117-18. Accordingly, we agree with the ALJ that the opinions of Respondents’ experts are entitled to little weight. ID at 58-59, n. 25.

Respondents also fail to point to any convincing evidence to support their contention that the moratorium increased the likelihood that the parties would release a Three Tenors Boxed Set and a Greatest Hits album. Although aggressive promotion of 3T1 and 3T2 during the launch of 3T3 might have diverted some sales of 3T3 to the other products (with consumers benefitting from lower prices), presumably there would have been at least as many total units sold during that period. This scenario may well have been less profitable for the joint venture, but it is not apparent that the parties’ possible decision in the future to release these additional Three Tenors products would have depended on achieving greater sales of 3T3, as opposed to sales of 3T1 or 3T2. A Warner executive testified that the decision whether to release a Greatest Hits album was not related to a moratorium on price discounting, and that, as of early 2001, the disappointing sales of 3T3 had not dissuaded Warner and PolyGram from planning to release a Three Tenors Boxed Set or a Greatest Hits album. JX 101 at 76, 110-11, 113-15. *See also* JX 24 (“PolyGram has insisted . . . on having these box set and ‘greatest hits’ rights in order to ‘hedge their bets’ and give us an additional source of income in case the 1998 album does not perform up to

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expectations.”).

At most, Respondents’ record citations suggest that some PolyGram and Warner executives harbored vague concerns that discounting and advertising of 3T1 and 3T2 during the launch of 3T3 might have “devalued” the Three Tenors “brand” (jeopardizing future demand for Three Tenors products) or resulted in customer confusion (leading customers to purchase a different album than intended or perhaps not purchase anything at all). JX 89 at 57-58; JX 94 at 80-82. Respondents, however, offer no evidence indicating that these are valid concerns.⁷¹ In 1994, PolyGram responded to the release of 3T2 by discounting and aggressively promoting 3T1; and during the Three Tenors world tours in 1996 and 1997, both companies mounted promotional campaigns, which included discounting in many markets. *See supra* Part I.C. There is no evidence that any of these promotional activities “devalued” the Three Tenors “brand,” unduly confused consumers, or otherwise threatened Three Tenors output.

IV. REMEDY

Having found a violation of Section 5 of the FTC Act, the Commission is empowered to enter an appropriate order to prevent a recurrence of the violation. The Commission has wide discretion in its choice of a remedy. *Federal Trade Commission v. National Lead Co.*, 352 U.S. 419, 428 (1957); *Jacob Siegel Co. v. Federal Trade Commission*, 327 U.S. 608, 611 (1946). “[T]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past,” but “must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity.”

⁷¹ Respondents’ argument about consumer confusion – that eliminating the “clutter and confusion” of competing products was “in the customer’s best interest,” JX 94 at 80 (Saintilan Dep.) – is similar to a justification that the Supreme Court rejected in *IFD*. *See* p. 22, *supra*.

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Federal Trade Commission v. Ruberoid Co., 343 U.S. 470, 473 (1952). The remedy selected, however, must be reasonably related to the violation found to exist. *Id.*; *Jacob Siegel*, 327 U.S. at 613.

The order we issue narrowly prohibits the Respondents from engaging in the conduct that we have concluded was unlawful without impeding their ability to engage in legitimate joint venture activity. Paragraph II of the order requires Respondents to cease and desist from entering into an agreement with a competitor to fix prices of, or restrict truthful or “nondeceptive” advertising for any audio or video product in the United States. Paragraphs III.A. and III.B. specifically provide that the order does not prohibit Respondents from entering into a written agreement to set prices of or restrict the advertising for any audio or video product if the agreement is reasonably related to a lawful joint venture and reasonably necessary to achieve its procompetitive benefits. Paragraphs III.C. and III.D. provide that the order does not prohibit Respondents from entering into a written agreement to set prices of or restrict the advertising for any jointly produced audio or video product. Paragraph III.E. provides that Respondents are not prohibited from complying with an industry code or ethical standard intended to restrict the marketing to children of audio and video products rated with a parental advisory. Paragraph III.F. provides that, in any action by the Commission alleging a violation of this order, the burden is on the Respondents to show that the challenged conduct satisfies the conditions of Paragraphs III. A-E.⁷² These provisions are clearly related to the law violation found to exist and no broader than necessary to prevent a

⁷² Respondents claim, without citing authority for the proposition, that this provision improperly reverses the substantive and procedural burdens under the antitrust laws. We disagree. Requiring Respondents to demonstrate a justification for conduct that is inherently suspect is consistent with the analytical framework set forth in the relevant cases and followed in this opinion.

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recurrence of the violation.

Paragraphs IV, V, VI, VII, and VIII set forth Respondents' compliance obligations under the order. We have altered the ALJ's proposed order by shortening Respondents' reporting obligations under Paragraph IV.B. from nine to five years. These provisions are designed to assist the Commission in monitoring compliance with the order, and they impose a small burden on Respondents.

Respondents argue that a cease and desist order is not supported in this case because there is no threat that similar conduct will recur. We disagree. The marketing challenge that gave rise to the Three Tenors moratorium – *i.e.*, the fear that a new release by one of Respondents' recording artists may lose sales to the artist's older albums owned by a competitor – is not unique to the Three Tenors. As one PolyGram executive explained:

For every major release in any record company there is always an element of anxiety because of big investment, because of big expectations, to make sure that everything is set up to deliver the quantities we need to make money on that project. There was not any difference on this one.

JX 97 at 42-43.

Recording artists often release material on more than one record label during their careers. Music labels often release an exclusive artist to a competing company for a particular project. Thus, many artists have catalog albums that appear on a label different from the label that releases the artist's new record. IDF 331-32. In addition, a music label may release an artist from an exclusive recording contract in return for a royalty on the artist's first album on a new label, giving the companies a shared financial interest in the success of a particular album. IDF 333. In such circumstances, Respondents will likely have the same incentives and opportunity to restrict the pricing or advertising of

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the artist's catalog albums that led PolyGram and Warner to enter into the Three Tenors moratorium agreement.

Respondent UMG is presently engaged in other joint venture activity – including a joint venture with Sony to distribute music over the Internet – that may provide similar incentives and opportunity to restrain competition. UMG, Sony, and other music companies will provide music to the joint venture on a non-exclusive basis, meaning that music products marketed by the joint venture may also be marketed through traditional retail outlets. Absent a cease and desist order, UMG and Sony may find it profitable to fix prices on product sold to retail stores so as to enhance the joint venture's sales. IDF 334.

We find that, under these circumstances, there is a reasonable risk that Respondents will repeat the unlawful conduct absent an order to cease and desist. See *United States v. W.T. Grant Co.*, 345 U.S. 629, 632 (1953); *Marlene's, Inc. v. Federal Trade Commission*, 216 F.2d 556, 560 (7th Cir. 1954); *Superior Court Trial Lawyers Ass'n*, 107 F.T.C. 510, 602 (1986).

V. CONCLUSION

At the conclusion of *Turandot*, the Princess – overcome by the power of love – has a dramatic change of heart. She gladly weds the new suitor and presumably becomes a more kindly ruler. Because we hardly expect those in the business world to act on the basis of such sentiments, we rely on laws and institutions to ensure that businesses adhere to the principles of free competition that keep our economy vigorous and maximize the welfare of consumers. The process of adjudication is vital to those laws, in that it serves to clarify the acceptable bounds of business conduct.

In this case, we find that the moratorium agreement between PolyGram and Warner unreasonably restrained trade and constitutes an unfair method of competition. Respondents' restraints on price discounting and advertising are inherently suspect, because experience and economic learning consistently

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show that restraints of this sort dampen competition and harm consumers. Respondents' only proffered justification is not cognizable because it represents a collusive determination that consumers should be deprived of the vigorous competitive offering of certain products to induce them to choose others. Competing businesses contemplating such strategies should be aware that they are antithetical to the fundamental policies of our antitrust laws and will not be countenanced.

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FINAL ORDER

The Commission has heard this matter on Respondents' appeal from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to affirm the Initial Decision and enter the following order. Accordingly,

I.

IT IS ORDERED that, as used in this order, the following definitions shall apply:

1. "PolyGram Holding" means PolyGram Holding, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by PolyGram Holding, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

2. "Decca Music" means Decca Music Group Limited, its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Decca Music Group Limited; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

3. "UMG" means UMG Recordings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by UMG Recordings, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

4. "UMVD" means Universal Music & Video Distribution Corp., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and

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affiliates controlled by Universal Music & Video Distribution Corp.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

5. “Respondents” means PolyGram Holding, Decca Music, UMG, and UMVD, individually and collectively.

6. “Commission” means the Federal Trade Commission.

7. “Audio Product” means any prerecorded music in any physical, electronic, or other form or format, now or hereafter known, including, but not limited to, any compact disc, magnetic recording tape, audio DVD, audio cassette, album, audiotape, digital audio tape, phonograph record, electronic recording, or digital audio file (*i.e.*, digital files delivered to the consumer electronically to be stored on the consumer’s hard drive or other storage device).

8. “Video Product” means any prerecorded visual or audiovisual product in any physical, electronic, or other form or format, now or hereafter known, including, but not limited to, any videocassette, videotape, videogram, videodisc, compact disc, electronic recording, or digital video file (*i.e.*, digital files delivered to the consumer electronically to be stored on the consumer’s hard drive or other storage device).

9. “Seller” means any Person other than a Respondent that produces or sells at wholesale any Audio Product or Video Product.

10. “Joint Venture Agreement” means a written agreement between a Respondent and a Seller that provides that the parties to the agreement shall collaborate in the production or distribution of Audio Products or Video Products (including, without limitation, through the licensing of intellectual property).

11. An Audio Product or Video Product is “Jointly Produced” by a Respondent and a Seller when, pursuant to a written

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agreement between such Respondent and such Seller, each contributes significant assets to the production or distribution of the Audio Product or Video Product (including, without limitation, personal artistic services, intellectual property, technology, manufacturing facilities, or distribution networks) to achieve procompetitive benefits. For example and without limitation, an Audio Product or Video Product is “Jointly Produced” by a Respondent and a Seller when (1) such product is manufactured or packaged by such Seller and sold at wholesale by such Respondent, or (2) such product is manufactured or packaged by such Respondent and sold at wholesale by such Seller.

12. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, partnerships, and unincorporated entities.

13. “Officer, Director, or Employee” means any officer or director or management employee of any Respondent with responsibility for the pricing, marketing, or sale in the United States of Audio Products or Video Products.

14. “United States” means the fifty states, the District of Columbia, the Commonwealth of Puerto Rico, and all territories, dependencies, and possessions of the United States of America.

II.

IT IS FURTHER ORDERED that Respondents shall cease and desist from, directly or indirectly or through any corporate or other device, in or affecting commerce (as “commerce” is defined in the Federal Trade Commission Act), soliciting, participating in, entering into, attempting to enter into, implementing, attempting to implement, continuing, attempting to continue, or otherwise facilitating or attempting to facilitate any combination, conspiracy, or agreement, either express or implied, with any Seller:

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A. To fix, raise, or stabilize prices or price levels in connection with the sale in or into the United States of any Audio Product or any Video Product; or

B. To prohibit, restrict, regulate, or otherwise place any limitation on any truthful, nondeceptive advertising or promotion in the United States for any Audio Product or any Video Product.

III.

IT IS FURTHER ORDERED that:

A. It shall not, of itself, constitute a violation of Paragraph II.A. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement to set the prices or price levels for any Audio Product or Video Product when such written agreement is reasonably related to a lawful Joint Venture Agreement and reasonably necessary to achieve its procompetitive benefits.

B. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement that regulates or restricts the advertising or promotion for any Audio Product or Video Product when such written agreement is reasonably related to a lawful Joint Venture Agreement and reasonably necessary to achieve its procompetitive benefits.

C. It shall not, of itself, constitute a violation of Paragraph II.A. of this Order for a Respondent and a Seller to enter into, attempt to enter into, or comply with a written agreement to set the prices or price levels for any Audio Product or Video Product that is Jointly Produced by such Respondent and such Seller.

D. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent and a Seller to enter into, attempt to enter into, or comply with a written agreement that regulates or restricts the advertising or promotion for any Audio

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Product or Video Product that is Jointly Produced by such Respondent and such Seller.

E. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement, industry code, or industry ethical standard that is: (1) intended to prevent or discourage the advertising, marketing, promotion, or sale to children of Audio Products or Video Products labeled or rated with a parental advisory or cautionary statement as to content, and (2) reasonably tailored to such objective.

F. In any action by the Commission alleging violations of this Order, each Respondent shall bear the burden of proof in demonstrating that its conduct satisfies the conditions of Paragraph(s) III.A., III.B., III.C., III.D. and III.E. of this Order.

IV.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent has complied and is complying with this Order.

B. One (1) year after the date this Order becomes final, annually for the next four (4) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, each Respondent shall file with the Commission a verified written report:

- (1) Setting forth in detail the manner and form in which it has complied and is complying with this Order; and
- (2) Identifying the title, date, parties, term, and subject matter of each agreement between any Respondent and any Seller, entered into or amended on or after the date this

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Order becomes final, that: (a) fixes, raises, or stabilizes prices or price levels in connection with the sale in or into the United States of any Audio Product or Video Product, or (b) prohibits, restricts, regulates, or otherwise places any limitation on any truthful, non-deceptive advertising or promotion in the United States for any Audio Product or any Video Product, other than those Audio Products and Video Products that are Jointly Produced.

PROVIDED, HOWEVER, that Respondents shall not be required to identify in their reports to the Commission any agreement that: (i) was previously identified to the Commission pursuant to Paragraph IV.B.2., and (ii) was not amended following such previous identification.

C. Each Respondent shall retain copies of all written agreements identified pursuant to Paragraph IV.B.2. above; and shall file with the Commission, within ten (10) days' notice to the Respondent, any such written agreements as the Commission may require.

V.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, upon written request, each Respondent shall permit any duly authorized representative of the Commission:

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A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of the Respondent relating to any matters contained in this Order; and

B. Upon five (5) days' notice to the Respondent and without restraint or interference from it, to interview officers, directors, or employees of the Respondent.

VII.

IT IS FURTHER ORDERED that each Respondent shall:

A. Within thirty (30) days after the date on which this Order becomes final, send a copy of this Order by first class mail to each of its Officers, Directors, and Employees;

B. Mail a copy of this Order by first class mail to each person who becomes an Officer, Director, or Employee, no later than (30) days after the commencement of such person's employment or affiliation with the Respondent; and

C. Require each Officer, Director, or Employee to sign and submit to the Respondent within thirty (30) days of the receipt thereof a statement that: (1) acknowledges receipt of the Order; (2) represents that the undersigned has read and understands the Order; and (3) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject the Respondent to penalties for violation of the Order.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate twenty (20) years after the date on which the Order becomes final.

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that PolyGram Holding, Inc., a corporation, Decca Music Group Limited, a corporation, UMG Recordings, Inc., a corporation, and Universal Music & Video Distribution Corp., a corporation, hereinafter sometimes collectively referred to as "respondents," have violated the provisions of said Act, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

1. Respondent PolyGram Holding, Inc. (“PolyGram Holding”) is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 825 Eighth Avenue, New York, New York 10019.
2. Respondent Decca Music Group Limited (“Decca Music”) is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at 347-353 Chiswick High Road, London, England W4 4HS. Decca Music is successor to, and was formerly named, The Decca Record Company Limited (“Decca Records”).
3. Respondent UMG Recordings, Inc. (“UMG”) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2220 Colorado Avenue, Santa Monica, California 90404. UMG is successor to, and was formerly named, PolyGram Records, Inc. (“PolyGram Records”).
4. Respondent Universal Music & Video Distribution Corp. (“UMVD”) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware,

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with its office and principal place of business located at 10 Universal City Plaza, Universal City, California 91608. UMVD became the successor corporation to PolyGram Group Distribution, Inc. ("PolyGram Distribution") when PolyGram Distribution merged with UMVD on May 1, 2000. PolyGram Holding, Decca Music, UMG, and UMVD are all subsidiaries or affiliates of Vivendi Universal S.A., a French corporation.

5. Warner Communications Inc. ("Warner") is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 75 Rockefeller Plaza, New York, New York 10019. Warner is a subsidiary of AOL Time Warner Inc.

6. Warner, acting directly and through certain subsidiaries (collectively, "Warner Music Group"), has for many years been engaged in the business of producing, marketing, and distributing pre-recorded music and videos in the United States and worldwide.

7. PolyGram N.V. ("PolyGram"), a Netherlands corporation, acting directly and through certain subsidiaries (collectively, "PolyGram Music Group"), was for many years engaged in the business of producing, marketing, and distributing pre-recorded music and videos in the United States and worldwide. Among the firms composing the PolyGram Music Group were PolyGram Holding, Decca Records, PolyGram Records, and PolyGram Distribution. In December 1998, PolyGram was acquired by The Seagram Company Ltd., a Canadian corporation. Two years later, The Seagram Company Ltd. merged with Vivendi S.A. and Canal Plus S.A., to form Vivendi Universal S.A.

8. The acts and practices of Warner, PolyGram Holding, Decca Records (predecessor to Decca Music), PolyGram Records (predecessor to UMG), and PolyGram Distribution (predecessor to UMVD), including the acts and practices alleged herein, are in commerce or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

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9. The Three Tenors is a musical joint venture consisting of renowned opera singers Luciano Pavarotti, Placido Domingo, and Jose Carreras. Beginning in 1990, The Three Tenors have come together every four years at the site of the World Cup soccer finals for a combination live concert and recording session. The concert promoter is responsible for producing the master recordings. Prior to each performance, the concert promoter selects one (or more) of the major music/video distribution companies to distribute compact discs, cassettes, videocassettes, and videodiscs derived from the master recordings.

10. Distribution rights to the original 1990 Three Tenors performance, entitled *The Three Tenors*, were acquired by PolyGram Music Group. Distribution rights to the follow-up performance, *The Three Tenors in Concert 1994*, were acquired by Warner Music Group.

11. In a contract dated December 19, 1997, Warner Music Group and PolyGram Music Group agreed to collaborate in the distribution of audio and video products derived from the next Three Tenors World Cup concert, scheduled for Paris on July 10, 1998. Among the important undertakings of the parties were the following:

- (a) Warner Music Group would secure from the concert promoter worldwide audio, home video, and television broadcast rights to the 1998 Three Tenors concert (the "Rights");
- (b) Warner Music Group would exploit the Rights within the United States;
- (c) Warner Music Group would license to PolyGram Music Group the right to exploit the Rights outside of the United States;
- (d) Warner Music Group and PolyGram Music Group would each be entitled to 50 percent of the net profits and net

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losses derived from the worldwide exploitation of the Rights (as well as from the production of a Greatest Hits album and/or a Box Set incorporating the 1990, 1994, and 1998 Three Tenors albums);

- (e) PolyGram Music Group would reimburse Warner Music Group for 50 percent of any advance paid to the concert promoter; and
- (f) other expenses incurred by either Warner Music Group or PolyGram Music Group in the exploitation of the Rights (*e.g.*, manufacture, advertising, marketing, and distribution) would be deducted from revenues for purposes of calculating net profits (losses).

12. Warner Music Group and PolyGram Music Group were concerned that the audio and video products that would be derived from the upcoming Three Tenors concert in Paris would be neither as original nor as commercially appealing as the earlier Three Tenors releases.

13. In 1998, Warner and certain other members of Warner Music Group, and PolyGram Holding, Decca Records, PolyGram Records, and PolyGram Distribution, entered into an agreement not to compete. PolyGram Holding, Decca Records, PolyGram Records, and PolyGram Distribution agreed not to discount and not to advertise the 1990 Three Tenors album and video from August 1, 1998 through October 15, 1998. In return, Warner and certain other members of Warner Music Group agreed not to discount and not to advertise the 1994 Three Tenors album and video from August 1, 1998 through October 15, 1998. The parties referred to their agreement not to compete worldwide during this period as the “moratorium.”

14. The third Three Tenors album and video, entitled *The Three Tenors -- Paris 1998*, were released in the United States on August 18, 1998, and were distributed in the United States by Warner Music Group. During the moratorium period, August 1

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through October 15, PolyGram Holding, Decca Records, PolyGram Records, and PolyGram Distribution refrained from discounting or advertising the 1990 Three Tenors album and video in the United States. During this period, Warner and Warner Music Group likewise refrained from discounting or advertising the 1994 Three Tenors album and video in the United States.

15. The moratorium agreement was not reasonably necessary to the formation or to the efficient operation of the joint venture between Warner Music Group and PolyGram Music Group.

16. The effect of the moratorium agreement among Warner, certain other members of Warner Music Group, PolyGram Holding, Decca Records, PolyGram Records, and PolyGram Distribution, as alleged herein, was to restrain competition unreasonably, to increase prices, and to injure consumers.

Violations Alleged

17. As set forth in Paragraph 13 above, Warner, PolyGram Holding, Decca Records (predecessor to Decca Music), PolyGram Records (predecessor to UMG), and PolyGram Distribution (predecessor to UMVD) agreed to restrict price competition, in violation of Section 5 of the Federal Trade Commission Act, as amended.

18. As set forth in Paragraph 13 above, Warner, PolyGram Holding, Decca Records (predecessor to Decca Music), PolyGram Records (predecessor to UMG), and PolyGram Distribution (predecessor to UMVD) agreed to forgo advertising, in violation of Section 5 of the Federal Trade Commission Act, as amended.

19. The acts and practices of respondents, as alleged herein, constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

Complaint

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a respondent in the complaint. Unless

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otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on October 29, 2001, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as amended, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including, but not limited to, an order that requires the following:

1. Each respondent shall cease and desist, either directly or indirectly, from entering into, seeking to enter into, continuing, or implementing any agreement to fix, raise, or stabilize prices or price levels, or to engage in any other pricing action in connection with the sale of any audio product or any video product.
2. Each respondent shall cease and desist, either directly or indirectly, from entering into, seeking to enter into, continuing, or implementing any agreement that prohibits, restricts, impedes, or places limitations on any truthful, non-deceptive advertising or promotion for any audio product or any video product.

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3. Each respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such respondent's chief executive officer stating that it will abide by the terms of this order, to each of its directors, officers, and employees.
4. Each respondent shall file periodic compliance reports with the Commission.
5. Each respondent shall take such other measures as are appropriate to correct or remedy, or to prevent the recurrence of, the anticompetitive practices engaged in by respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of July, 2001, issues its complaint against said respondents.

By the Commission.

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INITIAL DECISION

By James P. Timony, Administrative Law Judge

FINDINGS OF FACT

I. BACKGROUND

A. History

1. The Federal Trade Commission ("FTC") issued a complaint on July 31, 2001, alleging that Respondents PolyGram Holding, Inc. ("PolyGram Holding"), Decca Music Group Limited ("Decca MGL"), UMG Recordings, Inc. ("UMG"), and Universal Music & Video Distribution Corp. ("UMVD") agreed with competitor Warner Communications Inc. ("Warner Communications"): (a) to restrict price competition, and (b) to forgo advertising, violating Section 5 of the Federal Trade Commission Act.

2. On September 17, 2001, the Commission accepted a consent agreement with Warner Communications enjoining agreements with a competitor to fix prices or limit truthful, non-deceptive advertising or promotion. (Warner Communications Inc., C-4025 (Sept. 17, 2001)).

3. A trial of this matter commenced on March 5, 2002. Complaint Counsel called four witnesses. Anthony O'Brien, from Atlantic Recording Corp. (an affiliate of Warner Communications); Rand Hoffman, from PolyGram Holding; Professor Catherine Moore, the director of the Music Business Program at New York University; and Dr. Stephen Stockum, an economist. Respondents rested without calling any witnesses. Both sides introduced numerous documents and deposition testimony of 20 witnesses.

B. Three Tenors

4. The Three Tenors are opera singers Jose Carreras, Placido Domingo, and Luciano Pavarotti. Stip. P2. Since 1990, they sang

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every four years at the site of the World Cup soccer finals n1 for a live concert and recording session. Stip. P84.

n1 The World Cup is an international soccer tournament. The World Cup final match was located in Rome in 1990, in Los Angeles in 1994, and in Paris in 1998. Stip. P83.

5. The Three Tenors recorded three albums of arias and songs. The first album, The Three Tenors ("3T1"), was released in 1990 by PolyGram. The second album, Three Tenors in Concert 1994 ("3T2"), was released in 1994 by Warner. The third album, The Three Tenors--Paris 1998 ("3T3"), was released in 1998 by PolyGram and Warner. Stip. P85.

C. Respondents

6. Each of the four Respondents is a subsidiary of Vivendi Universal S.A., a French corporation. Stip. P5. Respondents UMG and UMVD are subsidiaries of Respondent PolyGram Holding. Stip. P14.

7. Respondent PolyGram Holding is a Delaware corporation with its office and principal place of business located in New York, NY. Stip. P6.

8. Respondent Decca MGL is a United Kingdom corporation with its office and principal place of business located in London, England. Decca MGL was formerly named, The Decca Record Company Limited ("Decca"). Stip. P7.

9. Respondent UMG is a Delaware corporation with its office and principal place of business located in Santa Monica, CA. UMG was formerly named, PolyGram Records, Inc. ("PolyGram Records"). Stip. P8.

10. Respondent UMVD is a Delaware corporation with its office and principal place of business located in Universal City, CA. UMVD is successor to PolyGram Group Distribution, Inc. ("PGD"). Stip. P9.

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11. PolyGram is a group of firms--affiliated with PolyGram N.V.--engaged in the producing, marketing, and distributing recorded music and videos in the United States and worldwide. Comprising Polygram in 1998 were PolyGram Holding, PolyGram Records, PGD, and Decca, all subsidiaries of PolyGram N.V. Stip. PP13, 15.

12. In 1998, Decca owned 3T1 and marketed the album. Stip. P95; F. 102-07. PolyGram Classics & Jazz ("PolyGram Classics"), a division of PolyGram Records, also had marketing responsibilities for 3T1. Stip. PP79, 132. PGD distributed 3T1 in the United States. Stip. P134. PolyGram Holding negotiated the collaboration between PolyGram and Warner with regard to 3T3. Hoffman, Tr. 406-07, 479; F. 65.

13. During 1998, PolyGram Holding provided services to its subsidiaries, including legal, financial, business affairs, and human resources services. Stip. P16; Hoffman, Tr. 287.

14. Decca was a music "label." Decca develops, acquires, and produces recorded music. Stip. P74. From 1990 to 1998, Decca owned the copyright to the master recording of 3T1. Stip. P95. Decca did business in the United States under the name London Records. Stip. P96.

15. In 1998, PolyGram Classics was a division of PolyGram Records. Stip. P17. PolyGram Classics was a "label group," assisting PolyGram labels, including Decca, Philips Classics, Deutsche Grammophon, and Verve. PolyGram Classics engaged in marketing, promoting, pricing and advertising 3T1 in the United States. Stip. PP79, 132.

16. In 1998, PGD distributed and sold audio and video products in the United States. Stip. P82. PGD serviced all of the PolyGram labels and joint ventures. Caparro Dep. (CX 609) at 12. During the 1990s, PGD executed PolyGram Classics' marketing strategy as it related to retailers. Caparro Dep. (CX609) at 25-26.

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17. Since 1990, compact disc, audio cassette, and video cassette versions of 3T1 were distributed in the United States by PGD, and by its successor UMVD. Stip. P91. PGD decided the wholesale price and the advertising strategy for audio and video versions of 3T1 sold in the United States. Stip. P133.

18. In December 1998, PolyGram N.V. was acquired by The Seagram Company Ltd. ("Seagram"). The music businesses of PolyGram N.V. (i.e., Polygram) combined with the music businesses of Seagram to form Universal Music Group ("Universal"). Two years later, Seagram merged with Vivendi S.A. and Canal Plus S.A., to form Vivendi Universal S.A. Stip. P18.

19. Most of the PolyGram employees in this case were with Universal after the merger, including: Chris Roberts, former President of PolyGram Classics; Rand Hoffman, the former Senior Vice President of Business Affairs for PolyGram Holding; Bert Cloeckert, the former Vice President for PolyGram in Continental Europe; and Kevin Gore, the former Senior Vice President and General Manager of PolyGram Classics. Stip. PP24, 26, 29, 32; Roberts Dep. Vol. 1 (JX 92) at 5-6, 8; Hoffman Dep. (JX 99) 6-7; Cloeckert Dep. Vol. 1 (JX 97) at 5-7; Gore Dep. (JX 87) at 6-7.

D. Warner

20. Warner Communications, a subsidiary of AOL Time Warner Inc., is a Delaware corporation with its office and principal place of business located in New York, NY. Stip. P19. Warner Music Group ("Warner") refers to a group of firms--affiliated with Warner Communications--engaged in the business of producing, marketing, and distributing recorded music and videos in the United States and worldwide. Among the firms comprising Warner are Atlantic Recording Corp. ("Atlantic") and Warner Music International ("WMI"). Stip. P20.

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21. Atlantic is a label engaged in the business of developing, acquiring, and producing recorded music. Atlantic operates primarily in the United States. Stip. P75.

22. WMI manages and coordinates the music operations of Warner operating companies located outside of the United States. Stip. P21.

E. Interstate Commerce

23. PolyGram and Warner are each vertically integrated producers and distributors of recorded music. Answer PP6-7. PolyGram and Warner distribute their products through operating companies ("opcos")--responsible for sales in a particular country. Stip. P148. In 1998, PolyGram Classics was the "opco" for the United States for classical music produced by PolyGram. Greene Dep. at 40.

24. Respondent PolyGram Holding, PolyGram Records (the predecessor to Respondent UMG) and PGD (the predecessor to Respondent UMVD) all engage in, or engaged in, acts and practices that affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. Stip. PP10-12.

25. In 1998, recorded music products produced by Decca, including 3T1, were distributed throughout the United States, primarily by PGD. Stip. PP76, 134; Caparro Dep. (CX 609) at 24-25. In 1998, PGD distributed recorded music and videos, including 3T1, to retailers in each of the fifty states and in the District of Columbia, and maintained a warehouse facility in Indiana from which it distributed recorded music and videos. Stip. P135; Caparro Dep. (CX 609) at 15, 24-25. Today, recorded music products produced by Decca MGL (including 3T1) are distributed throughout the United States, primarily by UMVD. Stip. P77.

26. Warner distributed 3T2 and 3T3 in the United States since 1994. O'Brien, Tr. 402-03; O'Brien Dep. (JX 100) at 19.

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PolyGram and Warner negotiated the Three Tenors moratorium agreement in the United States, including in a meeting in New York, NY in March 1998. F. 90; CX 382.

II. OLDER THREE TENORS RECORDINGS**A. The 1990 Three Tenors Concert**

27. The Three Tenors first performed together at the Baths of Caracalla in Rome, on the eve of the 1990 World Cup final match in July 1990. Stip. P86.

28. PolyGram acquired from the concert promoter distribution rights to recordings from the 1990 Three Tenors performance in Rome. CX 213; CX 215; Stip. P89. Compact disc, audio cassette, and video cassette versions of 3T1 were released by PolyGram in August 1990. Stip. P90.

29. 3T1 became the best-selling classical album of all time. Stip. P100. More than twelve million audio units, and three million video units of 3T1 have been sold worldwide. Stip. PP101-102. 3T1 was the number one classical album in the United States for 1991 and 1992, and was the third highest selling classical album for 1993. CX 584; CX 585; CX 586.

B. The 1994 Three Tenors Concert

30. On July 16, 1994, the Three Tenors performed at Dodger Stadium in Los Angeles, on the eve of the final match of the World Cup. Stip. P103. The 1994 Three Tenors concert was organized by concert promoter Tibor Rudas. CX 246 at 3TEN0007695. All of the major music companies, including PolyGram and Warner, vied to acquire distribution rights for products to be derived from the 1994 Three Tenors concert. CX 247 at 3TEN00011271.

31. During 1993, PolyGram negotiated with Rudas to acquire the right to distribute audio and video recordings of the 1994 Three Tenors concert. Stip. P104. PolyGram and Rudas were

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unable to agree upon the final terms of a contract. Kronfeld Dep. (JX 86) at 21-23; CX 228; CX 230; CX 231; Constant Dep. (JX 96) at 80-81.

32. Warner acquired from Rudas the right to distribute audio and video recordings of the 1994 Three Tenors concert. Stip. P105.

33. At the time of the 1994 concert, Pavarotti was obligated by contract to record exclusively for Decca. Stip. P108. In 1994, Decca agreed, in exchange for certain considerations, to waive its rights to the exclusive services of Pavarotti as a recording artist, thereby permitting Pavarotti to perform on an audio and video product distributed by Warner. Stip. P109.

34. Upon the release of 3T2 in 1994 and until 1998, PolyGram (3T1) and Warner (3T2) competed to sell their Three Tenors albums. F. 200-34.

35. Warner considered 3T2 to be a business success. F. 222; O'Brien, Tr. 406.

III. THE MORATORIUM AGREEMENT

36. In 1997, Warner and PolyGram agreed to collaborate on the distribution of products derived from the 1998 Three Tenors concert. Warner would distribute 3T3 in the United States, and PolyGram would distribute 3T3 outside of the United States. F. 59.

37. PolyGram and Warner were concerned that 3T3 would lose sales to 3T1 and 3T2. F. 234-35, 239, 268-73.

38. PolyGram and Warner agreed to a "moratorium" on the discounting and advertising of their older Three Tenors products in the weeks surrounding the release of 3T3. They agreed at a meeting in March 1998, in oral and written communications between PolyGram and Warner representatives in late June/early

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July 1998. F. 137-53. The agreement was approved by senior executives at PolyGram and Warner. F. 83, 95, 123, 152.

A. Agreement to Restrict Discounting and Advertising

39. PolyGram and Warner executives admit that there was an agreement to restrict discounting and advertising. F. 40-42.

40. In 1998, Anthony O'Brien was Executive Vice President and Chief Financial Officer of Atlantic Records, and Warner's principal contact with PolyGram for the 3T3 project. Stip. PP49, 50. O'Brien testified at trial that PolyGram and Warner agreed to restrict the discounting and advertising of 3T1 and 3T2 during 1998 in the United States and worldwide. O'Brien, Tr. 390.

41. Rand Hoffman, Senior Vice President for Business Affairs for PolyGram Holding during 1998, also acknowledged the existence of the moratorium agreement. Hoffman, Tr. 280.

42. Paul Saintilan, the Senior Marketing Director for Decca/PolyGram, acknowledged that PolyGram and Warner agreed to restrict the marketing of 3T1 and 3T2. Saintilan Dep. (JX 94) at 47-48.

43. Contemporaneous internal Warner and PolyGram business documents acknowledge that PolyGram and Warner agreed to limit the discounting and advertising of 3T1 and 3T2 for a period of time around the release of 3T3. JX 1; JX 2; JX 3; JX 4; JX 5 at UMG001527; JX 6; JX 9; JX 28 at UMG001487; JX 40; JX 42; JX 43 at UMG00479-80; JX 48; JX 62 at 3TEN00003536-38; JX 63; JX 64; JX 66; JX 72; JX 74; CX 204; CX 404; CX 429.

B. General Terms

44. PolyGram and Warner agreed to forgo discounts and promotions for the older Three Tenors products for the period from August 1, 1998 through October 15, 1998 (the "moratorium period"). O'Brien, Tr. 390, 443-44; Hoffman, Tr. 311-12; JX 4 at UMG000208; CX 202; JX 9-A.

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45. PolyGram and Warner agreed not to "aggressively" discount 3T1 or 3T2 during the moratorium period. Neither party would offer the older ("catalogue") Three Tenors products at a price that would provide an incentive to retailers to sell the product at a price below suggested retail price, or prominently to position the product in the store. O'Brien, Tr. 442-43; Hoffman, Tr. 311-12; JX 3; JX 9-A.

46. PolyGram and Warner agreed not to advertise or promote 3T1 or 3T2 during the moratorium. O'Brien, Tr. 390, 436; JX 1-A; JX 4 at UMG000208.

47. PolyGram and Warner agreed that the moratorium would apply to audio and video products. O'Brien, Tr. 446; Hoffman, Tr. 326; JX 4 at UMG000208; JX 9-A; CX 202; CX 203 at UMG004911.

48. PolyGram and Warner agreed that the moratorium would apply to the marketing of 3T1 and 3T2. O'Brien, Tr. 390; Hoffman, Tr. 312; JX 9-A.

49. PolyGram and Warner understood that, outside of the United States, there might be some discounting of catalogue Three Tenors products during the moratorium period. JX 74 at UMG000203.

50. PolyGram asked Anthony O'Brien that Atlantic not "overstock" retailers with 3T2 in the period prior to August 1, 1998. PolyGram did not want product sold by Atlantic prior to August 1 to be offered by retailers at a discount price after August 1, 1998. O'Brien instructed Atlantic's sales department not to overstock retailers in the United States in the period leading up to August 1, 1998. O'Brien, Tr. 444-45.

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IV. NEGOTIATION OF THE MORATORIUM**A. PolyGram and Warner Agree to Collaborate**

51. During 1996, concert promoter Tibor Rudas approached Warner to discuss the next Three Tenors project: a huge open-air concert in front of the Eiffel Tower scheduled to coincide with the World Cup finals in Paris in July 1998. CX 319 at UMG004205; O'Brien, Tr. 407.

52. Initially, Warner considered distributing the 3T3 products without a collaboration with PolyGram. O'Brien, Tr. 550-51; CX 317; CX 321 at 3TEN00004277; **CX 322** (in camera).

53. During the negotiation with Rudas, Warner was concerned that Rudas might make a deal for 3T3 with another music company. CX 354 at 3TEN00002271; **CX 355 at 3TEN00003298** (in camera).

54. During 1996, Rudas also discussed with PolyGram the possibility of PolyGram acquiring the rights to the 1998 Three Tenors concert. Stip. P122; CX 315. In November 1996, Decca/PolyGram executives negotiated with Rudas and requested PolyGram's senior executives' approval to make an offer for the rights to the 3T3 project; PolyGram did not anticipate collaboration with Warner. CX 327.

55. In 1998, as in 1994, Pavarotti was under exclusive contract to record for PolyGram. Stip. P125. In the spring of 1997, Ahmet Ertegun, the Chairman of Atlantic (a Warner subsidiary based in the United States) met with Alain Levy, his counterpart at PolyGram, "to ask that PolyGram allow Luciano Pavarotti to record the project for [Warner]." CX 366 at 3TEN00007334.

56. At the meeting, PolyGram's counter-offer was that Warner and PolyGram should "be partners for the 1998 concert project and all derivative product[s]." CX 366 at 3TEN00007334. See also JX 22 at UMG001342; CX 345 at UMG001635.

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57. Warner calculated that, on the conservative assumption that the third Three Tenors album sold only 60 percent as well as 3T2, then Warner and PolyGram would each make over \$ 5.5 million. CX 366 at 3TEN00007334. If the profits had been projected to be only \$ 3 million, Warner still would have gone ahead with the deal. O'Brien, Tr. 412.

B. PolyGram and Warner Negotiate

58. By a series of contracts dated October 14, 1997, in return for an \$ 18 million advance and other consideration, Rudas licensed to Warner the worldwide audio, video, and home television rights to the 1998 Three Tenors concert and a box set and greatest hit albums from 3T1, 3T2 and 3T3 (the "3T3 Rights"). Stip. P126; **JX 11** (in camera); **CX 205** (in camera); **CX 206** (in camera).

1. Specific terms of the collaboration

59. Pursuant to the Concert/License Agreement dated December 19, 1997, Warner and PolyGram agreed to collaborate on the distribution of products derived from the 1998 Three Tenors World Cup concert. The contract is formally between Warner Benelux B.V. and PolyGram S.A. Stip. P127; JX 10.

60. The contract between PolyGram and Warner provides that:

- a. Atlantic, a Warner affiliate, is responsible for exploiting the 3T3 Rights within the United States. JX 10-N. n2
- b. Warner licenses to PolyGram the right to exploit the 3T3 Rights outside of the United States. JX 10-N-O.
- c. Warner and PolyGram are separately responsible for developing and implementing marketing plans for their respective territories. Neither party has the right

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to approve or disapprove the other's marketing plans. JX 10-P, T. However, Warner and PolyGram agree to "consult and coordinate" with respect to marketing and promotion activities in connection with the exploitation of the 3T3 Rights. JX 10-P.

d. Warner and PolyGram are each entitled to 50 percent of the net profits and net losses derived from the worldwide exploitation of the 3T3 Rights (as well as from the production of a Greatest Hits album and/or a Box Set incorporating the 1990, 1994, and 1998 Three Tenors albums). JX 10-Q.

e. PolyGram agrees to reimburse Warner for 50 percent of the \$ 18 million advance paid to Rudas. JX 10-S.

f. Other expenses incurred by either Warner or PolyGram in the exploitation of the 3T3 Rights are to be deducted from revenues for purposes of calculating net profits (losses). JX 10-Q-S.

n2 To "exploit" a recording is a music industry term that encompasses selling, advertising, marketing, and promoting the album. O'Brien 422:6-11.

2. Limited covenant not to compete

61. In negotiating the terms of the 1998 Three Tenors project, PolyGram and Warner discussed the scope of a covenant not to compete. Several iterations of this contract provision were exchanged over a one month period. **CX 357** (in camera); **CX 359** (in camera); **CX 361** (in camera).

62. PolyGram and Warner decided that for four years following the release of 3T3, neither PolyGram nor Warner would release a new Three Tenors album. However, the contract provides that PolyGram shall be free to exploit 3T1, and that Warner shall be free to exploit 3T2.

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- a. The original draft of the Concert/License Agreement, prepared by PolyGram and forwarded to Warner on November 19, 1997, contained no covenant not to compete. **CX 357** (in camera); **Hoffman, Tr. 374** (in camera).
- b. On December 8, 1997, Warner requested that the draft Concert/License Agreement be modified to include a provision restricting both PolyGram and Warner from releasing a new Three Tenors album. **CX 358** at 3TEN00002443 (in camera). Warner was concerned that a new Three Tenors album would capture sales from 3T3 and diminish the profitability of the venture. O'Brien, Tr. 420.
- c. PolyGram was also concerned that a new Three Tenors album may interfere with sales of 3T3 and diminish its profitability. Hoffman, Tr. 305. PolyGram forwarded to Warner a second draft of the Concert/License Agreement. The second draft, dated December 15, 1997, includes a provision captioned "Holdback on Future Three Tenors Products." The Holdback Provision provides that neither PolyGram nor Warner shall release a Three Tenors album until June 2002. **CX 359 at 3TEN00002410** (in camera).
- d. On December 14, 1997, Warner communicated to PolyGram its request that the Holdback Provision be amended: **[redacted] [redacted] CX 359 at 3TEN00002410** (in camera).
- e. On December 15, 1997, PolyGram forwarded to Warner a revised version of the Contract/License Agreement. PolyGram amended the Holdback Provision so as to exclude any restriction on the exploitation of 3T1 and 3T2. **CX361 at 3TEN00002400** (in camera); O'Brien, Tr. 421.

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f. On December 18, 1997, Warner requested an additional modification to the Holdback Provision. **[redacted] [redacted] [redacted]** Thus, the draft contract was amended to prohibit--for a four year period--the repackaging of either 3T1 (by PolyGram) or 3T2 (by Warner). **CX 362 at 3TEN00002316** (in camera).

63. The parties' non-compete obligation is contained in Paragraph 9 of the final, executed Concert/License Agreement:

Holdback on Future "Three Tenors" Products:
Neither Warner nor PolyGram (nor any of their respective parents or affiliates) shall release any phonograph record or audiovisual device embodying the joint performances of all of the Artists (whether pre-existing or newly recorded), anywhere in the world, until June 1, 2002, unless such release is pursuant to this agreement. Nothing contained in this paragraph 9 shall be construed to prohibit (a) Warner from continuing to exploit the 1994 Album or (b) PolyGram from continuing to exploit the 1990 Album (as defined in the Rights Agreements).

JX 10-U-V at UMG001076-77.

64. As of the date the Concert/License Agreement was entered into, PolyGram did not know Warner's plans for the exploitation of 3T2 upon the release of 3T3. Hoffman, Tr. 305. As of the date the Concert/License Agreement was entered into, Warner did not know PolyGram's plans for the exploitation of 3T1 upon the release of 3T3. O'Brien, Tr. 501, 548.

65. Although the Concert/License Agreement is formally between Warner Benelux B.V. and PolyGram S.A., the Holdback Provision was understood by both parties to apply to all Warner affiliates and to all PolyGram affiliates. Hoffman, Tr. 305-07; O'Brien, Tr. 421-22. Rand Hoffman, the PolyGram Holding executive who negotiated the Concert/License Agreement,

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understood his role in these negotiations as representing all of PolyGram, and not just the French company (PolyGram S.A.) that ultimately executed the agreement. Hoffman, Tr. 307; Stip. P29.

3. Repertoire

66. Warner, Polygram and Rudas negotiated who would control the repertoire for the 1998 Three Tenors concert and recordings. Warner and PolyGram recognized that the success of the new Three Tenors album was tied to the repertoire. The music companies wanted to be sure that the repertoire on 3T3 would be "distinctive," and that it would not repeat selections from the earlier Three Tenors recordings. Roberts Dep. (JX 92) at 12-16; Hoffman, Tr. 300; O'Brien, Tr. 410; CX 331; CX 343; CX 402; CX 330 at UMG000512.

67. Warner and PolyGram proposed to Rudas that they should have the right to approve a significant part of the repertoire to be performed and recorded at the 1998 Three Tenors concert. **CX 322 at 3TEN00006987** (in camera); CX 337; CX 340 at 3TEN00000523; CX 349 at 3TEN00000520; CX 354 at 3TEN0002272; O'Brien, Tr. 410.

68. Rudas insisted that he and the artists should control the choice of songs. CX 334; O'Brien, Tr. 410.

69. In 1997, Phil Wild was Executive Vice President for Atlantic/Warner. In a memo to senior management, dated November 7, 1997, Wild identified the repertoire issue as one of the most significant business risks presented by the Three Tenors transaction. CX 354 at 3TEN00002272; see also CX 356 at 3TEN00002249; O'Brien, Tr. 418.

70. Wild's memo identifies and discusses several other "significant business risks" associated with the 3T3 transaction. Wild does not identify as a problem free-riding, consumer confusion, or difficulties in developing an effective marketing strategy for 3T3. CX 354 at 3TEN00002271-00002273.

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71. PolyGram and Warner agreed to forgo the right to approve the repertoire for the 1998 concert. CX 356 at 3TEN00002249; JX 22 at UMG001342; O'Brien, Tr. 418.

72. [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]

C. PolyGram and Warner Consider Ways to Distinguish 3T3

73. In 1996 and 1997, prior to agreeing to distribute 3T3, both PolyGram and Warner were concerned that the 1998 Three Tenors album would be neither as original nor as commercially appealing as the 1990 and 1994 releases. CX 318 at UMG004146, UMG004150; CX 321 at 3TEN000004277; CX 424 at UMG003563.

1. PolyGram and Warner seek to develop a unique identity for 3T3

74. PolyGram and Warner considered marketing strategies aimed at creating a unique identity for the 1998 album, distinct from the previous Three Tenors recordings. Saintilan Dep. (JX 94) at 101; CX 381 at 3TEN00000247; CX 386 at UMG004596; CX 423 at UMG003603.

75. PolyGram executives wished to differentiate the 1998 concert by including a guest performer. Stip. P128; Roberts Dep. (JX 92) at 25-27. However, this suggestion was rejected by the Tenors. Roberts Dep. (JX 92) at 25-26; CX 318 at UMG004150.

76. PolyGram considered the writing of original songs from Andrew Lloyd Webber, Elton John, Stevie Wonder, or from writers associated with Celine Dion, Barbra Streisand, Andrea Bocelli and Whitney Houston. CX 485 at UMG004182. See also CX 331 at UMG004183-184. These ideas were not implemented.

77. PolyGram and Warner discussed "positioning" themes for 3T3. Positioning means "creating an identity or a set of messages

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around a CD that differentiate [it] from other CDs." Saintilan Dep. (JX 94) at 61. For example, emphasizing "that it was a spectacular Parisian event, that it was an awesome spectacle with a completely different context from either the '94 album or the '90 album." Saintilan Dep. (JX 94) at 101-02.

78. The parties also recognized the desirability of designing packaging for the 1998 Three Tenors products that was "as different as possible from the two previous releases." CX 383 at UMG003284; JX 26 at UMG000372; Saintilan Dep. (JX 94) at 66-67.

2. Rudas promises an all-new repertoire

79. On January 6, 1998, Tibor Rudas publicly announced that the Three Tenors would perform in Paris in front of the Eiffel Tower, on July 10, 1998, as part of the World Cup celebrations. Rudas promised "a totally new repertoire of operatic arias and world-renowned popular songs." CX 380 at 3TEN00003979.

80. Rudas assured the music companies that the album to be recorded in Paris would consist of new songs not appearing on the prior two albums. CX 387 at UMG003148.

81. The message that 3T3 would contain all new repertoire was one of the promotional themes presented to the media by PolyGram and Warner. CX 477 at 3TEN00008809; Saintilan Dep. (JX 94) at 112; CX 496; JX 82 at UMG003855.

82. Despite the desire for all new repertoire for 3T3 to increase the likelihood of 3T3's commercial success, PolyGram and Warner concluded that the repertoire was disappointing. F. 133-36.

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V. MORATORIUM AGREEMENT**A. Not to Promote Catalogue Products**

83. The idea of a moratorium came from Chris Roberts, President of PolyGram Classics. Saintilan Dep. (JX 94) at 41. Roberts was concerned about the activities of PolyGram's own operating companies, and wanted to be sure that they did not promote 3T1 in a way that would divert sales from 3T3. Saintilan Dep. (JX94) at 41, 44-45. Roberts expressed this concern to Paul Saintilan, PolyGram's employee responsible for managing the marketing of 3T3. Saintilan Dep. (JX94) at 41-42.

84. In early 1998, Paul Saintilan relayed to PolyGram operating companies Chris Roberts' view that 3T1 should not be promoted in a way that captures sales from 3T3, during its release. PolyGram operating companies replied that if Warner was promoting 3T2, they wanted to be free to promote 3T1. Saintilan Dep. (JX 94) at 41-42; Saintilan Dep. (JX 94) at 46.

1. Marketing of older albums

85. On January 29, 1998, representatives of PolyGram and Warner first met to discuss "marketing and operational issues" relating to the release of 3T3. Saintilan Dep. (JX 94) at 56-57. The minutes of the January 29 meeting, prepared by Paul Saintilan shortly after the meeting, are in evidence as CX 383. Saintilan Dep. (JX94) 55-56.

86. The following persons attended the January 29, 1998 meeting: From Warner, Pat Creed, Vicky Germaise, and Margo Scott. From PolyGram, Chris Roberts (PolyGram Classics), Rand Hoffman (PolyGram Holding), Roger Lewis (Decca), and Paul Saintilan (Decca). Wayne Baruch, a representative of Rudas also attended. CX 383 at UMG003282; Saintilan Dep. (JX 94) at 56.

87. The marketing of 3T3 was discussed at the January 29, 1998 meeting. Chris Roberts (PolyGram Classics) raised with the group his "general concern" over how older Three Tenors

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products would be marketed upon the release of 3T3. Saintilan Dep. (JX 94) at 42-43. One option, Roberts indicated, was to "impose an ad moratorium until November 15." CX 383 at UMG00328; Saintilan Dep. (JX 94) at 72-73. There were "no concrete discussions" regarding the proposed advertising moratorium. Roberts raised the issue of advertising older Three Tenors albums, and suggested that it could be resolved at some future date. Saintilan Dep. (JX 94) at 42-43.

88. At the January 29, 1998 meeting, PolyGram and Warner did not reach any agreement. Saintilan Dep. (JX 94) at 73, 109-10.

89. At an internal PolyGram meeting on February 9, 1998, Saintilan noted that there were "No restrictions on 1990/1994 products." CX 386 at UMG004596.

2. Restrict the marketing of 3T1 and 3T2

90. The next meeting of PolyGram and Warner to discuss the 3T3 project was held in New York on March 10, 1998. CX 383 at UMG003289; Saintilan Dep. (JX 94) at 75. Between the January 29 meeting and the March 10 meeting, there had been no communications between PolyGram and Warner relating to the proposed Three Tenors moratorium. Saintilan Dep. (JX 94) at 75. Saintilan's notes from the March 10 meeting, prepared on or about March 10, 1998, are in evidence as JX 5. Saintilan Dep. (JX 94) at 110-11.

91. The following persons attended the March 10, 1998 meeting: From PolyGram, Roger Lewis (Decca), Paul Saintilan (Decca), Rand Hoffman (PolyGram Holding), and Alex Darbyshire (PolyGram Video). From Warner, Vicky Germaise, Pat Creed, and Margo Scott. Wayne Baruch representing Rudas also attended. JX 5 at UMG001523; Hoffman, Tr. 308-09.

92. At the March 10, 1998 meeting, PolyGram and Warner discussed the marketing of 3T1 and 3T2. Saintilan Dep. (JX 94) at 113. Saintilan's notes of the March 10, 1998 meeting state that, at

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the meeting, the parties agreed "that a big push on catalogue shouldn't take place before November 15." JX 5 at UMG001527; see also CX 388 at 3TEN0000800.

93. Catalogue is a music industry term that refers to older albums that continue to be offered for sale by a music company. Hoffman, Tr. 309-10; O'Brien, Tr. 394.

94. The agreement between PolyGram and Warner to forgo a "big push" on catalogue products was explained by Saintilan at his deposition. According to Saintilan, at the March 10, 1998 meeting, PolyGram and Warner agreed to observe a "window" or "moratorium" at the time of the release of 3T3 in which price discounting and promotion of 3T1 and 3T2 would not take place. Saintilan Dep. (JX 94) 115-16.

95. Roger Lewis, President of Decca, attended the March 10, 1998 meeting and discussed the marketing of 3T1 and 3T2. Lewis approved of the moratorium agreement. Saintilan Dep. (JX 94) at 117.

96. Saintilan understood that, at this meeting, a commitment to the moratorium was made by Decca for all PolyGram companies worldwide, including the PolyGram affiliates in the United States. Saintilan understood that a commitment to the moratorium was made by the Warner representatives on behalf of all Warner companies worldwide, including the Warner operating companies in the United States. Saintilan Dep. (JX 94) at 124-25.

97. During the March 10, 1998 meeting, the starting date for the moratorium was not specified. JX 5 at UMG001527.

3. The moratorium applied in the United States

98. The understanding reached by PolyGram and Warner at the March 10, 1998 meeting was that the moratorium on discounts and advertising would include all markets worldwide, including the United States. Saintilan Dep. (JX 94) at 116. PolyGram was

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concerned about possible discounting of 3T2 by Warner. Saintilan Dep. (JX 94) at 77.

99. In order for PolyGram to implement the moratorium in the United States, PolyGram needed the cooperation of PolyGram Classics and PGD. Saintilan Dep. (JX 94) at 49.

100. In 1998, Kevin Gore was the Senior Vice President and General Manager of PolyGram Classics in the United States. Stip. P26.

101. In the spring of 1998, Paul Saintilan spoke to Kevin Gore about the Three Tenors moratorium. This conversation took place in the United States. Saintilan told Gore that he (Saintilan) wanted PolyGram Classics to forgo discounting and advertising for 3T1 in the United States for a period of time. Gore responded that PolyGram Classics "would seek to comply." Saintilan Dep. (JX 94) at 49-50. Saintilan understood that Gore intended to communicate with PGD regarding the moratorium, and to ensure that PGD complied with its terms. Saintilan Dep. (JX 94) at 51.

B. Marketing Plans for 3T1

102. By memorandum dated February 27, 1998, Saintilan requested that each PolyGram operating company provide Decca/PolyGram with an outline of its local marketing campaign for 3T1 and 3T3. CX 417 at UMG003382. With regard to 3T1, Saintilan sought a description of planned marketing activities, expenditures, and target incremental sales. CX 417 at UMG003390-003391. The memo requested that the operating companies respond by March 18, 1998. CX 417 at UMG003382, 003390.

103. The opcos responded to Saintilan's request by submitting a description of planned marketing activities for 3T1. JX 50 at UMG003661-62. Several of the PolyGram operating companies planned price discounting and advertising campaigns for 3T1 during 1998. JX 50 at UMG003666, 003685, 003746; CX 427; JX 37.

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104. During 1998, the practice within PolyGram was that if an operating company wished to reduce the price of 3T1, that operating company was supposed to request and obtain the consent of both Decca (the repertoire owner) and PolyGram Vice President Bert Cloeckaert. Cloeckaert Dep. (JX 97) at 52; Cloeckaert Dep. (JX 98) at 176-77; CX 510 at UMG006328; CX 543 at UMG006214; Hoffman, Tr. 313.

105. In the spring of 1998, several Polygram operating companies formally requested permission from Decca and PolyGram to discount and promote 3T1. JX 35; CX 401; CX 402; CX 403; CX 404; CX 427. PolyGram operating companies wished to offer 3T1 at a discount price for all or part of the period running from August 1 to October 15, 1998. CX 403; CX 428; CX 429 at UMG003056; CX 442 at UMG000195; JX 35; JX 46.

106. PolyGram's reduction in the price of 3T1 in Europe during the pre-moratorium period did lead to higher sales levels. Cloeckaert Dep. (JX 97) at 81.

107. PolyGram instructed its operating companies: (i) that in view of the upcoming World Cup tournament, they could reduce the price of 3T1 and advertise its availability; but (ii) pursuant to an agreement with Warner, aggressive marketing campaigns in support of 3T1 would have to terminate by the end of July 1998:

a. "To keep in line with an agreement laid down with Atlantic and [PolyGram Classics President] Chris Roberts, we should not encourage any promotion on the original [Three Tenors] album from the day of release of the new album (probably in-store August 10) for a period of around 6 weeks." JX 40.

b. "We have agreed with Warners to discourage any promotion on the first [Three Tenors] album from the day of release of the new album . . . for a period of around 6 weeks. So all promotion on the

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first album should have stopped by then." CX 404 (emphasis in original).

c. "PolyGram has made an undertaking to Atlantic Records that no advertising or point of sale material originated for the launch of the new album will feature packshots of the 1990 album. This is based on Atlantic reciprocating by omitting the 1994 album in their initial POS [point of sale]/ads, and telling their opcos to back off promoting the 1994 album worldwide until a sufficient window has been observed." JX 28 at UMG001487.

d. "Following further discussions with Warners regarding the joint marketing of the 1998 '3 Tenors' album, it is now felt that we should avoid any aggressive price campaigns of the 1st '3 Tenors' album. This means that we will be unable to give consent to Germany and France for their campaigns and that we shall discourage any further requests from other opcos We do hope that you will appreciate that this decision is partly beyond our control and arises from a complex set of ongoing negotiations between PolyGram, Warners and the Rudas Organization." JX 42 (emphasis in original).

e. "After considerable discussion with Atlantic and other parties, the mid-price campaign first canvassed by Bert Cloeckert in Europe has also been reintroduced (mid-price royalty break available from Stephen Greene on application) Atlantic and PolyGram have agreed that we will jointly refrain from any promotion of the previous albums that could potentially undermine sales of the new album around the time of the initial release." CX 459 at UMG SK 0005.

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C. Warner Music International's Discount Campaign for 3T2

108. In April 1998, Chris Roberts, President of PolyGram Classics, instructed Paul Saintilan to "ensure" that Warner would comply with the moratorium agreement. JX 34.

109. Saintilan requested that Warner provide to PolyGram copies of Warner's internal directives to Warner operating companies instructing compliance with the moratorium agreement. JX 34.

110. During 1998, Pat Creed was Senior Director for Product Development for Atlantic Records, and was responsible for marketing and promotional activities for 3T3 in the United States. Stip. P36. Creed attended the March 10, 1998 marketing meeting at which the Three Tenors moratorium was first agreed upon by PolyGram and Warner. JX 5 at UMG001523.

111. On April 29, 1998, Saintilan (Decca/PolyGram) sent a letter to Creed (Atlantic/Warner) seeking assurance that Warner was planning to abide by the moratorium. The letter to Warner refers to PolyGram's written instructions to PolyGram operating companies requiring an end to discounting of 3T1 by July 24, 1998. Saintilan requested confirmation that Warner planned to "enforce the same window." JX 6.

112. Pat Creed forwarded Saintilan's April 29, 1998 letter to Anthony O'Brien, Executive Vice President and Chief Financial Officer of Atlantic. Creed's cover memo notes that Saintilan's letter includes "a copy of the message sent by Decca to their affiliates around the world. They are still looking for some sort of assurance from us that the same is being done for Warner Music International." CX 415 at 3TEN00010551.

113. Saintilan also sent a copy of his April 29, 1998 letter to Rand Hoffman (PolyGram Holding). Hoffman forwarded a copy of the letter to Margo Scott, an attorney for Warner. Hoffman, Tr. 320.

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114. Warner Music International ("WMI") personnel were not involved in planning for the release of 3T3, and were not aware of discussions concerning the moratorium. No WMI representatives attended any of the joint PolyGram/Warner marketing meetings, and there is no evidence that WMI was provided with any information regarding the marketing plans for 3T3. F. 86, 91.

115. In December 1997, WMI began planning a television advertising campaign for 3T2 to run in Europe from July through December 1998. WMI planned "to aggressively advertise, position and discount-price the 1994 album" throughout the second half of 1998. CX 443 at 3TEN00003641; CX 366 at 3TEN00007335; O'Brien, Tr. 414.

116. WMI forecast that dropping the wholesale price of the 3T2 from \$ 13.40 per unit to \$ 8.50 per unit, combined with an aggressive advertising campaign, would increase the company's sales of 3T2 by 170 percent. JX 31 at 3TEN00009930. In order to subsidize a price cut, in-store merchandising, and television and press advertising for 3T2, WMI asked Rudas to grant WMI a temporary reduction in royalties owed. JX 60 at 3TEN00003561. WMI assured Rudas that, given the anticipated increase in sales volume for 3T2, Rudas would garner higher profits at the lower royalty rate. JX 60 at 3TEN00003561; JX 31 at 3TEN00009930.

117. In May 1998, Tibor Rudas consented to a reduced royalty rate for the 3T2 audio and video products for the period from May to December 1998. CX 426 at 3TEN00003557-58; JX 60 at 3TEN00003561 ("to 1st Jan agree"); CX 431 at 3TEN00009923; CX 432; CX 434 at 3TEN00011049; CX 435 at 3TEN00017899; CX 436; CX 448 at 3TEN00011077-78.

118. On May 15, 1998, WMI issued a bulletin to its operating companies announcing the launch of a discount campaign for 3T2, effective from May 17, 1998 until December 31, 1998. CX 435 at 3TEN00017900.

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119. In June 1998, Polygram obtained a copy of WMI's bulletin announcing the discount campaign for 3T2, scheduled to run through December 1998. CX 425 at UMG000166-67.

120. PolyGram obtained information indicating that Warner would be selling 3T2 at a substantial discount. CX 429 at UMG003056; CX 441.

121. PolyGram's operating companies informed Saintilan and PolyGram's central management that they wanted to respond to Warner's price discounts on 3T2 by discounting PolyGram's 3T1. CX 425 at UMG000167; CX 429 at UMG003056; CX 440; CX 442 at UMG000194.

122. Rand Hoffman served as PolyGram's liaison with Warner for contract issues relating to the 3T3 project. In June 1998, Chris Roberts (PolyGram Classics) forwarded to Hoffman a note complaining that Warner was discounting 3T2 in Europe. JX 66.

123. Hoffman had attended the March 10, 1998 marketing meeting, and understood that PolyGram and Warner representatives had agreed to implement the moratorium. Hoffman, Tr. 280; JX 5 at UMG001523.

124. On June 11, 1998, Hoffman sent a letter to Warner. Hoffman, Tr. 322. Hoffman complained that in Denmark, and perhaps elsewhere in Europe, Warner was offering 3T2 at a "very low price." This action, Hoffman charged, contravened the understanding between PolyGram and Warner. Hoffman asked that Warner take steps to eliminate this discounting (JX 64).

125. Hoffman was not then aware that the moratorium period was scheduled to commence at the end of July. When informed of this fact, Hoffman revoked his letter. JX 66; Hoffman, Tr. 322-23; JX 63.

126. PolyGram understood that its central management did not have complete control over the prices charged by its operating companies, and understood that Warner had similar problems

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controlling its operating companies. Saintilan Dep. (JX 94) at 153. PolyGram therefore was concerned that it would be difficult for both companies to implement the moratorium consistently on a worldwide basis. Hoffman, Tr. 322; Saintilan Dep. (JX 94) at 153.

127. Chris Roberts, President of PolyGram Classics, advised that the moratorium agreement was likely to fall apart because of the mutual distrust between PolyGram and Warner at the level of the operating companies. Saintilan Dep. (JX 94) at 134-136; JX 66.

128. Saintilan distributed an e-mail message to PolyGram executives that PolyGram should not coax its operating companies to abide by the moratorium: If Warner discounted 3T2 in a local market, the PolyGram operating company would be permitted to "retaliate" with discounts on 3T1. Saintilan Dep. (JX 94) at 138; JX 66.

129. During June 1998, senior management at PolyGram felt that there was likely to be discounting and promotion of the older Three Tenors products upon the release of 3T3. Saintilan Dep. (JX 94) 139, 154. PolyGram did not modify its plans for advertising and promoting 3T3. Saintilan Dep. (JX 94) at 139.

130. PolyGram's response to the expectation that Warner would be discounting 3T2 upon the release of 3T3 was to notify its operating companies that they were free to retaliate by discounting 3T1. JX 9-B at 3TEN0000013; JX 1-B.

131. Anthony O'Brien and other executives at Atlantic/Warner became aware that Warner's international operation, WMI, was using a discount campaign to sell 3T2, and that the Three Tenors moratorium agreement was in jeopardy. JX 68.

132. On June 24, 1998, Atlantic forwarded a memo to Ramon Lopez, the President of WMI. Atlantic warned WMI that its price cut on 3T2 could lead PolyGram to discount its catalogue Three Tenors album. CX 443 at 3TEN00003641. Ramon Lopez,

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President of WMI, responded to Atlantic on July 1, 1998, insisting that PolyGram had initiated the price reduction. JX 8.

D. Repertoire for the Paris Concert

133. In June 1998, Rudas informed PolyGram and Warner of the intended repertoire for the upcoming Three Tenors concert. CX486-88. PolyGram and Warner were alarmed to learn that the intended repertoire for the 1998 Three Tenors concert was "not substantially new." CX 490; CX 489; O'Brien, Tr. 424-25. It would overlap with the repertoire of the earlier Three Tenors concerts: "4 out of the 5 songs Pavarotti is considering singing were performed in either 1990 or 1994. In addition, 7 of the 8 scheduled encores were performed in either 1990 or 1994." CX 489-90.

134. The parties were concerned that if the overlap in repertoire between 3T3 and the earlier Three Tenors albums was too extensive, then 3T3 could lose sales to 3T1 and 3T2. O'Brien, Tr. 426.

135. On several occasions from mid-June through to the date of the concert, PolyGram and Warner expressed to Tibor Rudas their dissatisfaction with the intended repertoire. CX 487; CX 489-90.

136. PolyGram and Warner understood that the Tenors' failure to deliver a new repertoire at the 1998 concert jeopardized the commercial success of the 1998 album and video. According to Warner executive Anthony O'Brien:

The problem that we had was that The Three Tenors [are] perhaps three of the laziest performers we have ever seen performing this type of music, and what we were hoping for, when we were making the '98 concert, was to have new and exciting repertoire. . . And they're not particularly given to sort of learning new arias, and so *Nessun dorma!* would come back again, or maybe Carreras would sing one of the

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Pavarotti songs or vice versa. And so although the album was different . . . it wasn't, perhaps, quite as new and exciting as we had hoped it to be.

O'Brien I.H. (JX101) at 74:2-16. Warner and PolyGram lost several million dollars on sales of 3T3. O'Brien, Tr. 523-25.

VI. POLYGRAM AND WARNER REAFFIRM THE MORATORIUM AGREEMENT

A. Oral Assurances

137. On June 25, 1998, Anthony O'Brien (Atlantic/Warner) and Paul Saintilan (Decca/PolyGram) discussed by telephone the Three Tenors moratorium. JX 9-A at 3TEN0000012; JX 74.

138. During the June 25, 1998 telephone conversation, Saintilan reaffirmed PolyGram's willingness to forgo discounting and advertising of 3T1, provided that Warner reciprocated with regard to 3T2. O'Brien assured Saintilan that his company, Atlantic, would comply with the moratorium agreement in the United States. O'Brien, Tr. 433.

139. O'Brien also told Saintilan that he would communicate with representatives of WMI to ensure that WMI would also abide by the moratorium. O'Brien, Tr. 433.

140. During the June 25, 1998 telephone conversation, O'Brien understood that Saintilan had the authority to agree, and did agree, to the moratorium on behalf of all of PolyGram. O'Brien, Tr. 434.

B. Further Assurances

141. On July 2, 1998, Paul Saintilan forwarded a letter to Anthony O'Brien confirming the terms of the moratorium, and requesting additional assurances that Warner intended to comply on a worldwide basis. The letter specifies that audio versions of

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3T1 and 3T2 will not be discounted or advertised for the period from August 1 to October 15, 1998. JX 9-E.

142. Later the same day, July 2, 1998, Paul Saintilan forwarded a revised letter to Anthony O'Brien confirming the terms of the moratorium, and requesting additional assurances that Warner intended to comply on a worldwide basis. The revised letter makes it clear that the proposed moratorium agreement should apply to both Three Tenors albums and Three Tenors videos. JX 9-A at 3TEN00000012.

143. O'Brien understood the July 2, 1998 letter from Saintilan to be for the purpose of detailing the terms of the moratorium. O'Brien, Tr. 434.

144. The two letters dated July 2, 1998 from Saintilan (Decca/PolyGram) to O'Brien (Atlantic/Warner) were sent to Rand Hoffman (PolyGram Holding) in New York, who forwarded them on to O'Brien (Atlantic/Warner). JX 9-A ("via Rand Hoffman") and JX 9-E ("via Rand Hoffman").

C. Follow-Up Letter

145. The Three Tenors performed in concert in Paris on July 10, 1998. O'Brien, Tr. 435.

146. O'Brien was in Paris on July 10 to attend the Three Tenors concert. O'Brien, Tr. 435.

147. On July 10, 1998, Saintilan (Decca/PolyGram) forwarded a follow-up letter to O'Brien (Atlantic/Warner) providing additional details regarding the implementation of the moratorium agreement, and again seeking formal confirmation of Warner's intention to comply on a worldwide basis:

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**re: THREE TENORS MORATORIUM ON 1990
& 1994 ALBUMS**

As discussed, we fully support a moratorium on the above albums which we strongly believe will be to our mutual benefit. The dates we are prepared to commit to are from August 1 to November 15 (subject to the qualifications in italics below).

The moratorium would constitute the following:

1. Advertising and promotion

The original 1990 album would not be advertised or promoted during this period. We have already omitted the 1990 album from all advertising and point of sale materials centrally originated for the new album.

2. Pricing

The original 1990 album would be sold at the top classical price point that it has historically traded at in each market

As discussed before, PolyGram operating companies have already been advised of the above moratorium, however we have informally allowed it to collapse at a local level to allow a response to Warners pricing. When we have a clear undertaking from Warners that the above agreement will be adhered to, we will re-enforce things from our side

So in summary, once a price agreement has been made, and we have clear

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evidence that Warners will enforce the moratorium, then we will re-enforce the moratorium on our side.

JX 1-A-B.

1. WMI

148. The PolyGram letters were distributed to senior executives within Warner, including Ramon Lopez, President of WMI. This led to a series of internal discussions. O'Brien, Tr. 434:-35, 437; CX 202; CX 457. Lopez acceded to the request of the Atlantic executives to comply with the moratorium between August 1, 1998 and October 15, 1998. O'Brien 437-39; JX 3; JX 2.

149. On July 13, 1998, WMI distributed a memorandum to Warner operating companies instructing that the company's discount campaign for 3T2 must end on July 31:

The previously announced period of the Three Tenors mid price campaign has changed. This campaign must now finish July 31st. No further discounting or new marketing activities which are not already in place may occur between August 1st and October 15th.

CX 458 at 3TEN00017892; See also JX 73; O'Brien, Tr. 438.

2. Atlantic relays WMI's assent to PolyGram

150. On July 13, 1998, Anthony O'Brien (Atlantic/Warner) telephoned Paul Saintilan (Decca/PolyGram) to confirm that WMI was on board and that the moratorium on discounting and promoting the older Three Tenors recordings would be honored throughout Warner. JX 3; JX 2; O'Brien, Tr. 440-41. O'Brien further informed Saintilan that WMI had issued a directive instructing all Warner operating companies to observe the Three Tenors moratorium. JX 3; JX 2.

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151. Saintilan independently confirmed (through a friend at Warner) that the directive had been issued throughout Warner. Saintilan was satisfied that the terms of the directive "complied perfectly" with his agreement with Warner. JX 4 at UMG000207.

3. PolyGram enforces the moratorium

152. Later that day, July 13, 1998, Saintilan forwarded an e-mail message to various PolyGram executives and managers describing his conversation with O'Brien, and informing them that the moratorium agreement was now securely in place at Warner:

Tony O'Brien advised today that Ramon Lopez had issued the directive through Warner that they will observe the moratorium from August 1 through to October 15. The exceptions will be in markets where four weeks notice of a price change is required. Lopez . . . believes that they should police us, and we should police them. The prices should be "normal" and not subject to any special discounts or promotion.

JX 3.

The recipients of Saintilan's July 13 e-mail message include Chris Roberts (President, PolyGram Classics), Kevin Gore (Senior Vice President, PolyGram Classics in the United States), Rand Hoffman (Senior Vice President, PolyGram Holding), and Roger Lewis (President, Decca). JX 3.

153. On or about July 14, 1998, Paul Saintilan (Decca/PolyGram) distributed a memorandum to PolyGram operating companies worldwide "re-enforcing" the company's intention to comply with the moratorium:

Ramon Lopez, the Chairman and CEO of Warner Music International issued a directive on July 13, that there should be no price discounting, advertising or promotion on the 1994 Warners Three Tenors album from August 1 until October 15. The only exceptions

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to this will be where legal obligations to retailers exist (such as four weeks notice of a price increase).

We now seek to re-enforce the moratorium on PolyGram's side, from August 1 to October 15, on a worldwide, not simply European basis. The moratorium prohibits price discounting, advertising and promotion of the 1990 album and video during this period

Should you find any evidence of Warners failing to comply with this agreement after August 1, please contact me providing as much detail as possible.

JX 4 at UMG000208; Saintilan Dep. (JX 94) at 171.

D. Intervention of PolyGram and Warner Attorneys

154. In late July 1998, after the Paris concert but prior to the release of 3T3, the legal departments of PolyGram and Warner became involved with the moratorium issue. F. 155, 160-63.

155. On July 17, 1998, Paul Saintilan forwarded his documents relating to the Three Tenors moratorium to PolyGram's General Counsel, Richard Constant. CX 459 at UMG SK 0001.

156. On July 30, 1998, Paul Saintilan forwarded a memorandum to PolyGram operating companies denying the existence of the moratorium agreement between PolyGram and Warner:

Contrary to any previous suggestion, there has been no agreement with Atlantic Records in relation to the pricing and marketing of the previous Three Tenors albums.

JX 76 at UMG000213.

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157. At trial, PolyGram executive Rand Hoffman acknowledged that Saintilan's statement that "there has been no agreement" was not correct. Hoffman, Tr. 367-68.

158. While disavowing the existence of a moratorium agreement, the July 30 memo also discourages any price discounting of 3T1:

With immediate effect Decca has concluded that it is appropriate to adopt a flexible position that allows operating companies the chance to make their own commercial decisions on the optimum pricing of the 1990 album. We should emphasize, however, that in deciding how to market and price the 1990 album, operating companies should take full account of PolyGram's massive investment in the 1998 album and the need to maximize returns on this investment.

JX 76 at UMG000213.

159. Saintilan's July 30, 1998 memorandum was likely understood by managers at the PolyGram operating companies as a pretense. They received at least three previous memoranda advising that there was an agreement between PolyGram and Atlantic restricting the discounting of previous Three Tenors albums. JX 43 at UMG000479-480; JX 4 at UMG000208. Although the memorandum purports to give discretion over 3T1 pricing to the operating companies, they understood that they still could not discount 3T1 without the express consent of Decca and Bert Cloeckert of PolyGram. Cloeckert Dep. (JX 98) at 175-76; Stainer Dep. (JX 89) at 80-81; Hidalgo Dep. (JX 88) at 110.

160. Attorneys for Warner and PolyGram reviewed a draft letter from O'Brien to Saintilan purporting to reject the moratorium agreement for non-U.S. markets. RX 706 at UMG SK 0021; RX 707 at UMG SK 0027; RX 708 at UMG SK 0030.

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161. On August 10, 1998, Anthony O'Brien was advised to sign and forward to Paul Saintilan a letter that the attorneys had drafted. O'Brien followed this advice. O'Brien, Tr. 452, 470.

162. The August 10, 1998 letter executed by O'Brien purports to reject the moratorium agreement, and asserts an intention to make unilateral decisions on pricing and promotion for 3T2. JX 81; O'Brien, Tr. 471.

163. On or about August 10, 1998, Anthony O'Brien had a final telephone conversation with Paul Saintilan regarding the moratorium agreement. O'Brien informed Saintilan that he (O'Brien) had been requested by counsel at Warner to send the August 10 letter. O'Brien further informed Saintilan that the August 10 letter notwithstanding, Atlantic and Warner Music International still intended fully to comply with the moratorium agreement. O'Brien, Tr. 470-71.

164. During the period August 1 through October 15, 1998, Anthony O'Brien understood that PolyGram was complying with the moratorium agreement. O'Brien, Tr. 472, 494-95.

E. Unfavorable Reviews

165. The 1998 Three Tenors album and video were released on August 18, 1998. O'Brien, Tr. 471.

166. Several music reviewers recognized the overlap in repertoire between the 1998 Three Tenors album and the earlier Three Tenors recordings. The Gazette (Montreal) (July 11, 1998) CX 575; The Seattle Times (Sept. 13, 1998) CX 580-B; The Boston Herald (Oct. 4, 1998) CX 579-B-C.

167. Published reviews of 3T3 were generally unfavorable: The San Francisco Chronicle (Oct. 4, 1998) CX 576; The Boston Globe at N1 (Oct. 4, 1998) CX 577-C; The Vancouver Sun at D12 (Sept. 26, 1998) CX 578-D; The Star-Ledger (Newark, NJ) (Sept. 26, 1998) CX 574-C; The Jerusalem Post at 9 (Sept. 2, 1998) CX 581-B.

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F. Marketing Campaign for 3T3 in the United States

168. Warner treated 3T3 as a high-priority record, and the marketing campaign for 3T3 in the United States was well-funded and in all media. Moore, Tr. 71. Warner's marketing campaign for 3T3 during 1998 included: the PBS broadcast of the Three Tenors concert in Paris, release of a single ("You'll Never Walk Alone") and a music video, six foot tall stand up floor merchandisers in the shape of the Eiffel Tower, newspaper and magazine ads, store circular, prominent positioning in retail stores (e.g., end caps, front counter displays, listening stations), radio spots, television ads, posters, mailers, New York City transit bus and rail ads, Access Hollywood feature to coincide with album release, E! Entertainment TV piece, and a web-site (featuring video interviews with the Tenors, conductor James Levine and Tibor Rudas, a tour of Pavarotti's dressing room and a fan bulletin board and chat room). CX 482-83. Warner's campaign for 3T3 in the United States included a cooperative advertising program with retailers that funded television and print advertisements. CX 483 at 3TEN00001423-1424; CX 482; Moore, Tr. 74-76, 82-83. Warner coordinated in-store displays for 3T3 and advertisements with major record chains. CX 483 at 3TEN00001418-1419; CX 482. This involved nameboards, four-color lightboxes, six-foot-tall stand-up floor merchandisers in the shape of the Eiffel Tower, window displays, end caps and posters. CX 482 at 3TEN00009048; Moore, Tr. 72-73, 79-83. Warner launched a publicity campaign with radio stations, release of an electronic press kit, a website, and solicitation of articles and reviews. CX 483 at 3TEN001425-1426; Moore, Tr. 76-79. Warner arranged to have the single "You'll Never Walk Alone" delivered to radio stations nationwide. Moore, Tr. 77-79, 234-35; CX 483 at 3TEN00001426.

169. Warner sought to increase sales of 3T3 by offering discounts to customers. The initial discount in the United States for 3T3 was seven percent to wholesale customers, and five percent to retail customers. CX 483 at 3TEN00001418.

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G. PolyGram and Warner Comply with the Moratorium Agreement in the United States

170. Atlantic (Warner) and PolyGram both complied with the moratorium agreement in the United States. O'Brien, Tr. 474-76.

171. Between August 1, 1998 and October 15, 1998, Atlantic (Warner) did not aggressively discount 3T2 in the United States; 3T2 was sold by Atlantic at full price only. O'Brien, Tr. 474.

172. Between August 1, 1998 and October 15, 1998, neither Atlantic (Warner) nor PolyGram funded advertising for 3T2 in the United States. O'Brien, Tr. 474; RX 728.

173. Between August 1, 1998 and October 15, 1998, Anthony O'Brien observed no discounting or advertising for 3T1 by PolyGram in the United States, and it was O'Brien's understanding that PolyGram was in fact complying with the moratorium. O'Brien, Tr. 476.

174. There is no evidence that during the moratorium period, PolyGram sold 3T1 at a discount price in the United States. See RX 713 at UMG004899-4900.

175. According to PolyGram's economic expert, Dr. Janusz Ordover, PolyGram's average wholesale price for 3T1 during the moratorium period (August/September/October 1998) was higher than the average wholesale price for 3T1 during the preceding three-month period (May/June/July 1998), and for the period August/September/October 1997. RX 716 (Ordover Expert Report) at P55.

176. Kevin Gore, Senior Vice President of PolyGram Classics during 1998 and currently President of Universal Classics, testified in his deposition that if he had found out that Warner was discounting 3T2 during the moratorium period, PolyGram's pricing and discounting decisions for 3T1 could have been affected. Gore Dep. (JX 87) at 111, 113.

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H. PolyGram and Warner Comply with the Moratorium Agreement Abroad

177. Warner complied with the moratorium agreement outside of the United States. O'Brien, Tr. 474; CX 453.

178. Between August 1, 1998 and October 15, 1998, Warner did not discount or advertise 3T2 outside of the United States. O'Brien, Tr. 474.

179. During the moratorium period, Warner's international operation (WMI) monitored PolyGram's prices for 3T1 outside of the United States. CX 450 at 3TEN00009904. If PolyGram were cheating on the agreement, then WMI wanted to respond by discounting and advertising 3T2. O'Brien, Tr. 476-77; CX 450 at 3TEN00009904.

180. Anthony O'Brien received no complaints from WMI during the moratorium period concerning PolyGram's marketing activities in support of 3T2. O'Brien, Tr. 476-77.

181. From August 1, 1998 through October 15, 1998, Warner perceived that PolyGram was substantially complying with the moratorium agreement outside of the United States. CX 204; O'Brien, Tr. 477.

I. Discounting on 3T2 After the Moratorium Expired

182. On October 2, 1998, Ramon Lopez (President, WMI) asked Val Azzoli (Co-Chairman, Atlantic) to contact PolyGram and discuss an orderly transition away from the moratorium. CX 204.

183. On October 15, 1998, the agreed-upon term for the Three Tenors moratorium came to an end. JX 3.

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VII. EACH OF THE RESPONDENTS AND THE MORATORIUM

184. Respondent Decca, through its employees Paul Saintilan and Roger Lewis, agreed to the Three Tenors moratorium. F. 92, 95, 110-13, 137-47, 150.

185. Respondent UMG (formerly PolyGram Records), through its employees Chris Roberts (President, PolyGram Classics division) and Kevin Gore conceived the Three Tenors moratorium. Roberts supervised Paul Saintilan with regard to the moratorium. F. 83-89, 101, 108, 122, 152, 155. PolyGram Records was responsible for the marketing for 3T1 in the United States, and it instructed PGD to comply with the moratorium. F. 15, 101.

186. Respondent PolyGram Holding, through its Senior Vice President Rand Hoffman, participated in the moratorium agreement. Hoffman attended the March 1998 meeting at which PolyGram and Warner first agreed to the moratorium. F. 91. Hoffman urged Warner to induce its operating companies to comply with the moratorium agreement. F. 122-25. Hoffman was responsible for the PolyGram/Warner collaboration, and corresponded with Warner about the moratorium agreement. F. 113, 144, 152. PolyGram Holding approved the actions of its subsidiaries PolyGram Records and PGD with regard to the moratorium.

187. Respondent UMVD (formerly PolyGram Group Distribution, or "PGD") participated in the moratorium in the United States by selling 3T2 at the conspiracy price during the moratorium period. Gore Dep. (JX 87) at 28-29; Caparro Dep. (CX 609) at 44-45. PGD executed the strategy developed by Decca and PolyGram Classic for marketing of 3T1 in the United States. F. 16-17, 101.

188. "PolyGram was a labyrinth of companies set for specific legal and tax purposes." Kronfeld Dep. (JX 86) at 15. In their dealings with Warner concerning the 3T3 and the moratorium, the

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PolyGram companies acted as a single entity. F. 65, 95-96, 124, 140.

189. Hoffman of PolyGram Holding, negotiated the moratorium with Warner on behalf of all of PolyGram. F. 65, 124.

190. Representatives from several different PolyGram companies (including Saintilan of Decca, Hoffman of PolyGram Holdings, and Roberts of PolyGram Records) attended the 3T3 meetings where the moratorium was discussed. F. 86, 91.

191. Decca's Saintilan sought approval for the moratorium from employees of PolyGram Records, including Chris Roberts. F. 127-28, 152, 155; JX 3-4. Saintilan corresponded regarding to the moratorium with PolyGram Holding's Rand Hoffman, and sought Hoffman's approval regarding the moratorium. F. 113.

192. PGD implemented the moratorium in the United States at the direction of Decca and PolyGram Records. F. 101.

193. Warner representative Anthony O'Brien understood that Paul Saintilan had the authority to agree to the moratorium on behalf of all of PolyGram. Saintilan believed that he was agreeing to the moratorium on behalf of all of PolyGram. F. 96, 140; JX 1-A-B.

194. As one of the entities responsible for the pricing of 3T1 in 1998, PolyGram Records had actual authority to determine the price of 3T1 charged by PGD in the United States. F. 15

195. As one of the entities responsible for the pricing of 3T1 in 1998, Decca had actual authority to determine the price of 3T1 charged by PGD in the United States. Gore Dep. (JX 87) at 98-99.

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**VIII. OTHER NEW THREE TENORS ALBUMS
RELEASED WITHOUT RESTRAINTS****A. Sony's Three Tenors Recording Without a Moratorium**

196. In 1999, Luciano Pavarotti was obligated by contract to record exclusively for PolyGram. CX 224 at UMG004248. In 1999, PolyGram agreed to waive its exclusive rights to the recording services of Pavarotti so as to permit Pavarotti to record a Three Tenors album for Sony. CX 515; CX 516.

197. In October 2000, Sony released an album derived from a performance of the Three Tenors in Vienna. The album is entitled The Three Tenors Christmas, and consists of Christmas songs from around the world. O'Brien, Tr. 482; Gore Dep. (JX 87) at 66-67.

198. Sony did not discuss with Warner restricting its competitive marketing activity in support of 3T2 and 3T3 at the time of the release of the 2000 Three Tenors album. O'Brien, Tr. 482.

199. Sony did not discuss with PolyGram restricting its competitive marketing activity in support of 3T1 and 3T3 at the time of the release of the 2000 Three Tenors album. Hoffman, Tr. 329.

B. In 1994, Warner Released 3T2 Without A Moratorium

200. In 1994, Warner controlled the rights to 3T2, while PolyGram controlled the rights to 3T1. Stip. PP85, 90, 106. 3T2 was distributed and marketed by Warner without any agreement between Polygram and Warner concerning Polygram's pricing or marketing of 3T1. Stip. P149.

201. During 1994, the marketing of 3T2 was a priority for Warner. Moore, Tr. 89-90; CX 247 at 3TEN00011271; CX 241 at 3TEN000007230.

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202. In its marketing campaign for 3T2, Warner anticipated that PolyGram would advertise and discount 3T1 when Warner released 3T2. CX 257; CX 249 at 3TEN00011254; CX 256 at 3TEN0004763, 4765-66; CX 258 at 3TEN00005402; CX 255; CX 244.

203. Warner's marketing effort was to differentiate 3T2 from 3T1. CX 259 at 3TEN00011109; CX 249 at 3TEN00011254-55; CX 242 at 3TEN00000441; CX 248 at 3TEN00011260.

204. Warner launched an aggressive and expensive international marketing campaign in support of 3T2. CX 247 at 3TEN00011271; O'Brien, Tr. 405-06; Hidalgo Dep. (JX 88) at 46-47; Stainer Dep. (JX 89) at 10.

205. Warner's marketing campaign for 3T2 in the United States was comprehensive and expensive. CX 243 at 3TEN00007150-58; Moore, Tr. 92-96; CX 251.

206. Warner offered compensation to secure prominent placement of 3T2 in music stores. CX 251 at 3TEN0008888-89; CX 249 at 3TEN00011253; CX 259 at 3TEN00011110.

207. Warner's U.S. and European operating companies offered key accounts a five percent discount for all orders taken in advance of the first shipment. CX 253 at 3TEN00011247. Warner also developed promotional programs to increase initial sales, including the introduction of a gold CD. CX 260 at 3TEN00011224; CX 332.

208. In the United States, Warner established a distinct identity for 3T2, and had a successful launch. CX 261 at 3TEN00017820; CX 262 at 3TEN00017828; CX 263 at 3TEN00017843; CX 264 at 3TEN00017822; CX 265 at 3TEN00017852.

209. Tibor Rudas was pleased with Warner's "total commitment and aggressive promotion" of 3T2. CX 325 at UMG004698.

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210. PolyGram did not sit back and permit the release of 3T2 to eclipse sales of 3T1. PolyGram developed an aggressive campaign to increase sales of 3T1, employing discounting and advertising. JX 29.

211. PolyGram instructed its opcos to promote the "original" Three Tenors concert and recordings as "unique and unrepeatable." CX 272 at UMG000524. See also CX 270 at UMG005050; CX 256 at 3TEN00004766.

212. During 1994, PolyGram launched a marketing campaign in support of 3T1 which distinguished this product through the use of product stickers, new posters, promotional discs for radio, and a deluxe edition. CX 283 at UMG005013; CX 272 at UMG000526-527; CX 271 at UMG005828; CX 270 at UMG005051. PolyGram used television advertising. CX 276 at UMG005033; CX 281 at UMG005028; CX 258 at 3TEN0005402-5403.

213. In the United States, PolyGram spent \$ 109,471 in cooperative advertising for 3T1 during 1994. JX 103 at UMG006407. PolyGram spent most of this money (nearly \$ 60,000) in September 1994, the month following the release of 3T2. JX 103 at UMG006407.

214. During 1994, PolyGram offered 3T1 at discounted prices. CX 275 at UMG005820; CX 256 at 3TEN0004766; CX 279 at UMG005031; CX 258 at 3TEN0005402; JX 44.

215. PolyGram reduced the wholesale price of 3T1 during 1994 by changing the list price to retailers; in some sales territories PolyGram moved 3T1 from the company's "top" price tier to the "mid-price" tier. E.g., JX 32; CX 400; CX 428; CX 249 at 3TEN00011254.

216. PolyGram also offered special discounts, while maintaining the "top" tier designation for this album. In the United Kingdom, PolyGram ran a successful campaign called "Three Tenors for under a Tenner," in which 3T1 was offered for

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less than 10 pounds. CX 273; Stainer Dep. (JX 89) at 38. PolyGram's U.K. operating company offered these incentives without reducing the wholesale list price. CX 275 at UMG005820.

217. PolyGram provided cooperative advertising funds to retailers. This method was used in the United States. JX 103 at UMG006407. Cooperative advertising is a monetary commitment that the label makes to a retailer for positioning the album in a desirable location in the store or including the album in an out of store advertisement placed by the retailer. Kopecky Dep. (CX 610) at 21-22; Moore, Tr. 47-48, 58-59.

218. When PolyGram provides cooperative advertising funds, the retailer deducts the value of the cooperative advertising from the amount it pays for product purchased from PolyGram. Kopecky Dep. (CX 610) at 28-29. Cooperative advertising programs are a form of discount. **CX 603-P** (in camera).

219. In September 1994--the first full month after the release of 3T2--PolyGram spent \$ 57,178 on cooperative advertising for 3T1 in the United States. JX 103 at UMG006407. During that same time period, PolyGram generated \$ 630,738.00 in U.S. sales of 3T1. RX 713 at UMG004889. PolyGram returned to retailers through 3T1 cooperative advertising programs approximately nine percent of the money 3T1 generated.

220. Cooperative advertising funds create an incentive for retailers to place the advertised product on sale in order to move a higher volume of product. Moore, Tr. 67; JX 105-I (Moore Expert Report). When music companies provide cooperative advertising for their products, the retail price for consumers tends to decrease. Moore, Tr. 65-66; Gore Dep. (JX 87) at 79-80. It is likely that retail prices of 3T1 in the United States following the release of 3T2 were lower.

221. Warner observed later: "In 1994, at the time of our release of the Three Tenors album, Decca dropped the price of their album to a midprice level. This was a temporary move by

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Decca to ensure sales of their recording at the time of our release of the 1994 album. At the end of 1994 Decca returned the pricing of the 1990 album back to the full line price." JX 32.

222. Competition from PolyGram notwithstanding, the 3T2 project was a business success for Warner. O'Brien, Tr. 406. See also CX 266 at 3TEN0009901. During 1994, Warner [redacted] achieved platinum sales on ship out of 3T2 in the United States and numerous other countries. CX 394 (in camera); CX 260 at 3TEN00011224. 3T2 was the second-best selling classical album in the United States in 1994, and was the top-selling classical album in 1995. CX 587-88.

223. There is no evidence that Warner's spending in support of 3T2 was negatively affected by PolyGram's campaign for 3T1. In fact, the head of Warner's marketing campaign in the United Kingdom during 1994 (who later worked for PolyGram) testified in his deposition that PolyGram's 1994 campaign probably helped Warner's release. Stainer Dep. (JX 89) at 13-14; see also CX 249 at 3TEN00011254-55.

C. PolyGram and Warner Compete Directly and Aggressively During the Three Tenors World Tour

224. During 1996 and 1997, The Three Tenors had concerts in Tokyo, London, Munich, New York, Johannesburg, and Melbourne. Stip. P117. Warner and PolyGram capitalized on the opportunity to drive sales of their Three Tenors products. CX 289; Stip. PP118-119; see also F. 225-34.

225. PolyGram offered 3T1 at a discounted price in many markets. CX 305 at 3TEN00004983; CX 307; CX 400.

226. In 1996, PolyGram released a World Tour Commemorative Edition of the 1990 concert, digitally re-mastered on a gold CD. PolyGram placed promotional stickers on the albums to draw consumer attention to the product enhancement. Stip. P121; CX 288 at UMG006106; CX 272 at UMG000526.

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227. Warner viewed the 1996/1997 Three Tenors tour to be "a powerful marketing tool" and "an ideal opportunity to exploit our product and new variants again." Stip. P118; CX 294 at 3TEN00017902; CX 295 at 3TEN00005917; CX2 96 at 3TEN0005910.

228. In 1996, Warner issued a special "Three Tenors World Tour Edition" of 3T2, consisting of the original 1994 Three Tenors CD, new packaging, and a booklet of unpublished photographs and information about The Three Tenors. Stip. P120; CX 296 at 3TEN00005912; CX 299 at 3TEN00005904. Warner offered "the concept of value added in the form of the slip case and celebratory photo book to counter the anticipated price cutting by Decca." CX 300 at 3TEN00008946. The slip case contained cover art different from that contained on the original 3T2 cover. CX 301; CX 302.

229. Warner instructed its operating companies to develop marketing plans for 3T2 that took advantage of the Three Tenors concert tour. CX 294 at 3TEN000017902; CX 293 at 3TEN011189; CX 299 at 3TEN0005903-04.

230. To counter PolyGram's marketing activities for 3T1, Warner's marketing campaign highlighted the advantages of the 1994 album. CX 299 at 3TEN00005903.

231. The Three Tenors performed in New York in July 1996. At that time, Warner launched a major television campaign in support of 3T2. CX 298 at 3TEN00010826.

232. At the time of the 1996 world tour, PolyGram assured Tibor Rudas that the rivalry between Warner and PolyGram would be beneficial for The Three Tenors:

Warner and we [PolyGram] will fight head on for every inch of advantage we could possibly gain over each other in exploiting the 3T tour with our respective product. Fair enough, competition is good for the business Nevertheless, be assured the

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competition will be lively and the whole project will greatly benefit from it.

CX 309.

233. By 1996, Warner had sold more than eight million units of the 3T2 album and video, including more than two and a half million units in the United States. CX 306 at 3TEN00004902.

234. The Three Tenors albums, 3T1 and 3T2, were both among the best-selling classical recordings in the United States in calendar years 1994, 1995, 1996, and 1997. CX587-90.

IX. COMPETITIVE EFFECTS OF THE MORATORIUM AGREEMENT

235. PolyGram and Warner agreed that each would not to discount 3T1 and 3T2. JX 104-B (Stockum Expert Report); Stockum, Tr. 586.

236. When horizontal competitors enter into an agreement to restrict price competition, the potential adverse effect is obvious. Stockum, Tr. 583085; JX 104-B (Stockum Expert Report). Complaint Counsel's economic expert, Dr. Stephen Stockum, testified at trial that the potential effect of an agreement between competitors not to discount includes a loss to consumer welfare and to allocation efficiency. Stockum, Tr. 583-85; JX 104-B (Stockum Expert Report).

237. Dr. Stockum concluded that, absent an efficiency justification, an agreement not to discount is very likely to be anticompetitive. Stockum, Tr. 581-86.

238. Price discounting is a marketing tool in the recorded music industry. Moore, Tr. 44-45, 65-68; Stockum, Tr. 600-02.

239. PolyGram and Warner offer discounts to retailers in order to increase sales levels. This principle applies to the sale of catalogue products as well as new releases. O'Brien I.H. (JX 101)

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82; **O'Brien Dep. (JX 100) at 91-92** (in camera); Caparro Dep. (CX 609) at 49-50, 33, 43-44; Kopecky Dep. (CX 610) at 12; Cloeckaert Dep. (JX 97) at 25-26; Stainer Dep. (JX 89) at 9-10; Greene Dep. (JX 95) at 58; Saintilan Dep. (JX 94) at 69-70.

240. During 1994, PolyGram responded to the release of 3T2 by aggressively reducing the price of 3T1 in many markets. F. 214-21.

241. In 1996 and 1997, PolyGram offered discounts on 3T1 in order to compete with Warner's marketing of 3T2 and its special World Tour Edition. CX 308; F. 224-32.

242. In 1998, many PolyGram and Warner operating companies determined that the best way to capitalize upon the public's revived interest in the Three Tenors was by dramatically reducing the price of these products (with aggressive advertising campaigns). F. 103-05, 115-18.

243. In 1998, both PolyGram and Warner requested and received assurances that the other would abide by the moratorium on discounting. F. 84, 107-13, 121, 126, 130, 132, 137-43, 147-48, 152-53.

244. Consumers consider price in their decisions to purchase classical music. CX 540 at UMG006114; CX 541 at UMG006151.

245. Information disseminated through advertising educates consumers about the availability and quality differences among competing products, sales locations, means of purchase, and pricing. This information promotes low prices and competition. JX 104-C (Stockum Expert Report); Stockum, Tr. 587-92; Moore, Tr. 53-54, 59, 62-64.

246. Economists have studied the effect of advertising restrictions in numerous industries. These studies conclude that advertising restrictions result in consumers paying higher prices. JX 104-C-D (Stockum Expert Report); Stockum, Tr. 592-600. In

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the absence of the ability to advertise a low price, a firm has less incentive to charge a low price. Stockum, Tr. 589-92; Ordoover Dep. (JX 90) at 49.

247. Dr. Stockum considered these studies in his expert opinion. JX 104-C-D (Stockum Expert Report); Stockum, Tr. 592-600. One study that showed that advertising bans of a short duration can lead to higher prices; it involved a newspaper strike in New York, where supermarkets advertised heavily. For about a 60 day period, there were no advertisements in Queens, while in neighboring Nassau County a different paper continued to operate. The author found that the prices rose by 5.8 percent during the very first week of the strike. Stockum, Tr. 599-600; Amihai Glazer, Advertising, Information and Prices--A Case Study, 19 Econ. Inquiry 661 (1981).

248. On the basis of economic theory and empirical findings, Dr. Stockum concluded that, absent an efficiency justification, Respondents' agreement not to advertise or promote catalogue Three Tenors albums is very likely to be anticompetitive. JX 104-D (Stockum Expert Report); Stockum, Tr. 587-92, 616-17.

249. Respondents' economic expert, Dr. Ordoover testified at his deposition that naked agreements between competitors not to advertise their respective products "are likely to be adverse to consumers." Ordoover Dep. (JX 90) at 47.

250. Advertising is an important basis of rivalry in the recorded music industry. Moore, Tr. 59; Stockum, Tr. 601-02; Caparro (CX 609) at 59; Kopecky Dep. (CX 610) at 50; Gore Dep. (JX 87) at 90.

251. Music companies spend huge amounts of money advertising recorded music products in the United States. Caparro Dep. (CX 609) at 57, 59; O'Brien I.H. (JX 101) at 12-13.

252. Between July 1994 (release of 3T2) and August 1998 (moratorium), aggressive and successful advertising campaigns were run separately by Warner and Polygram to increase sales of

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their respective Three Tenors products. F. 103-07, 115-18, 200-34.

253. In 1994 and thereafter, PolyGram used advertising to tell consumers that 3T1, was still the best performance and was still widely available at a discounted price. F. 210-18; see also JX 12 at UMG005007; Stainer Dep. (JX 89) at 38-39; Cloeckaert Dep. (JX 97) at 81.

254. In 1994 and thereafter, Warner used advertising to create a distinct identity for 3T2, and to suggest that it was the superior product. F. 200-09; see also CX 259 at 3TEN00011109; CX 249 at 3TEN00011254-55; CX 254 at 3TEN0005589-0005590; Stainer Dep. (JX 89) at 10-11; Stainer Dep. (JX 89) at 17-18.

255. During 1998, Warner proposed to Tibor Rudas an aggressive marketing campaign for 3T2. Warner's strategy was "to aggressively advertise, position, and discount price the 1994 album." JX 31 at 3TEN00009930; JX 7 at 3TEN00001492; O'Brien I.H. (JX 101) at 99-100; JX 29 at 3TEN00003592; JX 32 at 3TEN000011058.

256. Warner forecast that by cutting the wholesale price of 3T2 and advertising on television and in other media, the company could increase sales by 170 percent and increase overall profits as well. CX 396 at 3TEN00011072; JX 31 at 3TEN00009930.

257. During 1998, PolyGram authorized its operating companies to sell 3T1 at significantly discounted prices, supported by an advertising campaign. JX 41 at UMG003075; JX 43 at UMG000479-481; CX 413 at UMG003058.

258. PolyGram's operating companies forecast substantial additional sales of 3T1 if they were permitted to discount and advertise. JX 35; Cloeckaert Dep. (JX 97) at 57-58; JX 50 at UMG003746; CX 427.

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259. Advertising of recorded music creates demand, and discounting by music companies is more likely to occur. Stockum, Tr. 589-91; JX 104-C (Stockum Expert Report) at P8; Ordover Dep. (JX 90) at 49; Caparro Dep. (CX 609) at 55-56; see also Cloeckaert Dep. (JX 97) at 23-24, 52-53; Saintilan Dep. (JX 94) at 71; Moore, Tr. 64-65, 67.

260. When music companies advertise their products, the retail price for consumers tends to decrease. Moore, Tr. 65-66; Gore Dep. (JX 87) at 79-80.

261. Respondents chose a moratorium on discounting and advertising in order to achieve their goal of limiting the sales of 3T1 and 3T2. Stockum, Tr. 614.

X. EFFICIENCY JUSTIFICATION

A. Purpose of the Collaboration

262. During the hearing, Respondents stipulated that the Three Tenors moratorium was not necessary to the formation of the PolyGram/Warner collaboration:

MR. PHILLIPS: First of all, Your Honor, we have never contended that the moratorium agreement was necessary to the formation of the joint venture. The moratorium agreement, the evidence suggests, was not discussed before the formation of the joint venture. That's simply a nonissue in the case, Your Honor.

JUDGE TIMONY: Okay.

MR. PHILLIPS: [The President of PolyGram Classics] did approve the deal, but the moratorium agreement hadn't been discussed at the time he approved the deal, so how could he know, remember something that hadn't occurred.

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JUDGE TIMONY: You'd stipulate that?

MR. PHILLIPS: That the moratorium agreement hadn't been entered into before the joint venture was formed?

JUDGE TIMONY: And was not necessary to the agreement.

MR. PHILLIPS: It wasn't necessary to their entering into the deal, correct.

JUDGE TIMONY: Because they hadn't discussed it.

MR. PHILLIPS: Because they didn't discuss or even think about it. Because they didn't discuss or even think about it.

PHC Tr. 83-84.

263. PolyGram and Warner executed the written contract for 3T3 on December 19, 1997, months before entering into the moratorium agreement. Compare JX 10 with JX 5 at UMG001527; and CX 388 at 3TEN0008009 (same). PolyGram and Warner were committed to the formation of the PolyGram/Warner collaboration, the production of the Paris concert, the creation of 3T3, and the distribution of 3T3 in the United States well before discussions of the moratorium even commenced. The moratorium was not necessary for the 3T3 project.

264. If no moratorium on competition had been agreed to by PolyGram and Warner, Warner would still have distributed 3T3 in the United States; Warner was not going to walk away from its \$ 9 million investment. O'Brien, Tr. 446-47; Stockum, Tr. 623. Respondents estimate that the moratorium made only a small contribution to the value of the PolyGram/Warner collaboration. RX 716 (Ordoover Expert Report) at P35; Stainer Dep. (JX 89) at 46, 49-51; Saintilan Dep. (JX 94) at 106.

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265. At the time that PolyGram and Warner executed their agreement to collaborate on the distribution of 3T3, the firms retained the unconstrained right to exploit their respective Three Tenors catalogue products, 3T1 and 3T2. JX 10 at UMG001843-844. PolyGram's rights to 3T1 pre-date the arrangement and were not part of the collaboration for 3T3.

266. PolyGram's U.S. marketing operation was not involved in the 3T3 collaboration, and thus was not used efficiently for the betterment of the collaboration. Gore Dep. (JX 87) at 59, 60.

267. PolyGram's U.S. distribution assets were uninvolved in the distribution of 3T3. Caparro Dep. (CX 609) at 24-25, 39-40.

268. The parties were concerned that 3T3 might lose sales to 3T1 and 3T2. O'Brien, Tr. 490.

269. The parties were concerned that competition among Three Tenors products may adversely affect the profitability of the 3T3 project. Anthony O'Brien, the Warner executive responsible for the moratorium agreement, testified at trial that the purpose of the moratorium was to prevent consumers from selecting a lower priced alternative to 3T3. O'Brien, Tr. 485-87.

270. Warner received no profit from sales of 3T1 (owned by PolyGram), a smaller profit from each sale of 3T2 (substantial royalty owed to Rudas), and a larger profit from each sale of 3T3. O'Brien, Tr. 406; Hoffman, Tr. 300-01. Warner did not want consumers to compare the recordings and to determine that a catalogue Three Tenors album "is just fine for a few dollars less." O'Brien, Tr. 485-87.

271. Rand Hoffman, PolyGram's representative in the United States also testified that the function of the moratorium was to deter consumers from purchasing 3T1 and 3T2, with the expectation that such consumers would by default select 3T3. Hoffman I.H. at 43.

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272. This strategy, Hoffman expected, would protect the venturers' investment in the new Three Tenors album. Hoffman I.H. at 47.

273. Paul Saintilan, the PolyGram manager responsible for negotiating the moratorium agreement, testified at his deposition that the purpose of the moratorium was that without it: "consumers would choose, instead of buying the new album, to take advantage of the cheaper price of the old album and buy the old album." Saintilan Dep. at 90; see also JX 9-A.

274. Chris Roberts, the President of PolyGram Classics during 1998, professed not to know the purpose of the moratorium. Roberts Dep. (JX 93) at 141-45.

275. Stephen Greene was identified as a witness for the efficiency justifications proffered by Respondents. Stip. P64. He was unable to identify any risks to 3T3 if the older albums were promoted around the time of the release of 3T3. Greene Dep. (JX 95) at 192-94.

B. Free-Riding

276. The assumption underlying the free-riding defense is that, "some consumers who come to the store, because of the promotion of the 1998 Album and intending to buy that album, may [in the absence of the moratorium] be attracted by the cheaper 1990 and 1994 albums and buy them instead." RX 717 (Wind Expert Report) at P5(b). There is potential consumer harm only if the free-riding is so pervasive that Warner declined to advertise 3T3 in an appropriate manner at the time that the album was released. See RX 716 (Ordover Expert Report) at P30-32; Stockum, Tr. 624, 730, 739-41.

1. Diversion of sales

277. That advertising for one product may benefit another company's product is a ubiquitous phenomenon. Stockum, Tr.

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625-26, 629, 633; CX 612 (Stockum Rebuttal Expert Report) at P17; Wind Dep. (JX 91) at 126-27.

278. Respondents' expert, Dr. Wind, testified in his deposition that there are "tons of examples" of one firm capitalizing upon the marketing activities of a competitor. Wind Dep. (JX 91) 133-34. Dr. Wind explained that sellers generally respond to this challenge by sharpening their marketing campaigns, and by using advertising and other marketing tools to create a distinct identity for the target product. Wind Dep. (JX 91) at 125-29.

279. The "spillover" effect of advertising is a "fact of life" and the prospect of free-riding does not lead sellers of consumer products to abandon advertising. Stockum, Tr. 635-36; CX 612 (Stockum Rebuttal Expert Report) at P17; Kopecky Dep. (CX 610) at 55; Caparro Dep. (CX 609) at 85.

280. Within the recorded music industry, advertising intended to benefit one album often leads to sales of competing albums. RX 716 (Ordover Expert Report) at P36; Ordover Dep. (JX 90) at 130; Cloeckaert Dep. (JX 98) at 122-23; Moore, Tr. 59.

281. A strong, popular album creates spillover effects that are beneficial to the entire recorded music industry. For this reason, both labels and retailers often blame slow overall store traffic on the absence of heavily-advertised major new releases during a particular fiscal quarter. JX 105-F (Moore Expert Report) at P23; Cloeckaert Dep. (JX 97) at 46; Kopecky Dep. (CX 610) at 52-54; Caparro Dep. (CX 609) at 83-85.

282. In 1994, as Warner was preparing to market 3T2, it anticipated competition from PolyGram (3T1). F. 200, 202.

283. Warner advertised 3T2, and did not enter into a moratorium with its rival. F. 200-09.

284. Instead, Warner devised a marketing campaign aimed at convincing consumers that 3T2 was preferable to 3T1. F. 203.

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The company's marketing campaign for 3T2 was a success and 3T2 was profitable. F. 222, 223.

285. In 1996 and 1997, Warner was anxious to distribute 3T3 independently, with no prospect of a moratorium with PolyGram. CX 321 at 3TEN00004277.

286. In 1996 and 1997, PolyGram (certainly aware of its own marketing activity in 1994), was anxious to distribute 3T3 independently, with no prospect of a moratorium with Warner. CX 323 at UMG000487-88; CX 324 at UMG004669; CX 327 at UMG004679. Other music companies also were interested in distributing 3T3, with no prospect of a moratorium with PolyGram and Warner. CX 317.

287. The fourth Three Tenors album, Three Tenors Christmas, was produced and marketed by Sony in 2000 without restricting competition from 3T1, 3T2 or 3T3. F. 197-99.

288. Advertising in support of 3T3 would not have been curtailed on account of free-riding. Stockum, Tr. 637-38. Witnesses representing both Warner and PolyGram testified that 3T3 would have been promoted without the moratorium, and that the moratorium had no effect on the resources for advertising and promoting 3T3. "I think that 3T3 would have been appropriately marketed and promoted in the United States without regard for the moratorium with PolyGram." O'Brien, Tr. 490. See also O'Brien, Tr. 448; Roberts Dep. (JX 92) at 50-52.

289. Paul Saintilan testified that PolyGram's advertising budget for 3T3 was determined in January or February 1998, before the moratorium was agreed upon. After February 1998, there was little opportunity for PolyGram to increase or decrease marketing expenditures for 3T3. And even if there were such an opportunity, PolyGram did not view competition from Warner as a rationale for altering its advertising expenditures. Saintilan Dep. (JX 94) at 88-89; Saintilan Dep. (JX 94) at 194-95.

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290. In June 1998, when it appeared to PolyGram that the Three Tenors moratorium would fall apart, PolyGram did not alter its marketing strategy or cut back on its advertising budget. The company notified its operating companies that if Warner was found selling 3T2 at discounted prices in any territory, then the local PolyGram operating company could respond by discounting 3T1. F. 129, 130.

291. Before the moratorium, PolyGram executives were not concerned that PolyGram operating companies would not use their best efforts to promote 3T3 at the time of the launch, regardless of whether they were allowed to discount 3T1 or Warner discounted 3T2. Greene Dep. (JX 95) at 89-90, 189-90.

2. Free-riding defense

292. In 1998, PolyGram and Warner did not quantify the extent to which consumers drawn to record stores by promotion for 3T3 would (absent the moratorium) have purchased 3T1 or 3T2. O'Brien, Tr. 491; Saintilan Dep. (JX 94) at 82.

293. That PolyGram or Warner executives may have been concerned that 3T3 may lose sales to 3T1 and 3T2 is not a reliable gauge of the magnitude of the free-riding effect. Cloeckaert Dep. (JX 97) at 42-43.

294. Dr. Ordoover calculated that absent the moratorium agreement the sales diverted from 3T3 to 3T1 in the United States due to free-riding during the moratorium period (August - October 1998) would have been small (less than \$ 86,000 per month). RX 716 (Ordoover Expert Report) at P35; Ordoover Dep. (JX 90) at 158. Dr. Ordoover was unable to conclude that free-riding in the United States would have had a significant impact on the venturers' incentives to advertise 3T3. Ordoover Dep. (JX 90) at 158-59.

295. Dr. Ordoover acknowledged that discounting and promotion of 3T1 by PolyGram might increase Warner's incentive to promote 3T3. Ordoover Dep. (JX 90) at 115-16, 118-19.

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296. Dr. Ordover testified that he "cannot answer the question" whether the moratorium was reasonably necessary for the efficient marketing of 3T3 in the United States. Ordover Dep. (JX 90) at 55. He does not conclude that free-riding was a significant problem for PolyGram and Warner in the United States - only that it was a plausible concern. Ordover Dep. (JX 90) at 66; Ordover Dep. (JX 90) at 36-37. Dr. Ordover did not consider any less restrictive alternatives to the moratorium. Ordover Dep. (JX 90) at 77.

297. Although Dr. Ordover's report states that the moratorium is "reasonably necessary" to avoid free-riding (apparently outside the United States), he defines "reasonably necessary" as meaning plausible, or not obviously pretextual. Ordover Dep. (JX 90) at 50-51.

298. Dr. Ordover contends that "a quick look of restraints would be best left for those joint ventures that are a sham." He further argues that any restraint related to a legitimate joint venture should be analyzed under the fullest rule of reason. Ordover Dep. (JX 90) at 44. As a result, Dr. Ordover did not determine whether the restraint in this case actually promoted the efficient operation of the venture, or whether the efficiency justifications were valid.

299. For these reasons Dr. Ordover's testimony is given little weight.

3. Sharing of advertising expenses

300. A method of addressing a free-riding problem associated with advertising is to ensure that all those who benefit from such advertising contribute toward the funding for the advertising. CX 612 (Stockum Rebuttal Expert Report) at P25; Stockum, Tr. 816-18; Ordover Dep. (JX 90) at 94, 96.

301. The collaboration agreement between Warner and PolyGram provides that the two music companies shall each be entitled to 50 percent of the net profits and net losses derived

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from sales of 3T3 worldwide. Any advertising or marketing expenses incurred by either party are to be deducted from revenues for purposes of calculating net profits (losses). Every dollar spent in the United States by Warner to promote 3T3 is partially reimbursed by PolyGram; fifty cents comes from each of the venturers. Stockum, Tr. 735; JX 10-Q at UMG001072; JX 10-I at UMG0001075; O'Brien, Tr. 419-20; CX 348 at UMG002158; JX 20; CX 532 at 3TEN00009949; CX 533; CX 534 at UMG000577.

302. If the proportional benefit to each party of the advertising is equivalent to the proportional cost of advertising borne by each party, then there is no distortion of incentives. For example, if Warner paid 50 percent of the cost of advertising 3T3, and received 50 percent of the benefit that is an efficient arrangement. Stockum, Tr. 819-20; Ordoover Dep. (JX 90) at 114-15.

303. If the forecasted benefit to PolyGram and Warner from advertising 3T3 were not equal, then the parties could have altered the cost-sharing mechanism accordingly. For example, if Warner were expected to gain 52 percent of the benefit of the advertising, then the parties could have agreed that Warner would pay 52 percent of the cost. Stockum, Tr. 820-21.

304. It is efficient for PolyGram and Warner to allocate advertising costs based upon forecast (rather than actual) sales levels because Warner's advertising expenditures in support of 3T3 in the United States were also based upon forecast rather than actual sales levels. Stockum, Tr. 820-22; CX 321 at 3TEN00004279; Saintilan Dep. (JX 94) at 88-89, 194-95; O'Brien, Tr. 542; 401.

305. If PolyGram and Warner were unable to make a reasonably reliable forecast regarding the relative benefits from advertising 3T3, then each party's contribution to the advertising of 3T3 could have been determined by the parties after the launch of 3T3. Stockum, Tr. 822-23.

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4. Free-riding in the United States

306. Respondents' economic expert, Dr. Ordover, opined that if there were any serious free-riding problem in connection with the marketing of 3T3, it existed in Europe, but not the United States. Ordover Dep. (JX 90) at 36-37; Ordover Dep. (JX 90) at 25, 27.

307. There is no evidence that, during the moratorium period, discounted copies of 3T1 and 3T2 would have been resold, or transshipped, from the United States to Europe.

308. PolyGram considered transshipment to be a problem only within Europe. When PolyGram ran a campaign to discount 3T1 during June and July 1998, it was concerned about ensuring that prices in Europe were roughly equivalent, or "harmonized." JX 40. No effort was made to "harmonize" prices between Europe and the U.S. Cloeckert Dep. (JX 97) at 12-13; Gore Dep. (JX 87) at 24.

5. Making 3T3 more distinct from 3T1 and 3T2

309. Firms generally respond to spillover by "emphasizing the uniqueness of their offering." Wind Dep. (JX 91) at 127, 129.

310. Dr. Ordover acknowledged that the free-riding problem would be ameliorated if 3T3 were more distinct from 3T1 and 3T2, in repertoire and appearance. Ordover Dep. (JX 90) at 126, 130, 144; RX 716 (Ordover Expert Report) at P16.

311. In 1994, Warner used the tools of marketing (e.g., packaging, advertising) to create a unique identity for 3T2, distinct from 3T1. F. 203-08. A similar strategy could have been pursued for 3T3 in 1998. Moore, Tr. 123-35.

C. Consumer Confusion

312. Paul Saintilan was concerned that consumers would find it confusing to choose among three different Three Tenors

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albums. This concern was not based upon research, data, or observation. Saintilan Dep. (JX 94) at 81-82.

313. There is no evidence that consumers were confused in selecting among the Three Tenors albums. Hidalgo Dep. (JX 88) at 84-85. It was "speculation." Greene Dep. (JX 95) at 193, 195; Stainer Dep. (JX 89) at 42-43.

314. PolyGram designed the cover art for 3T3 and could have designed packaging for 3T3 that was distinct from the older Three Tenors products. CX 500; CX 501; CX 502; CX 503; CX 505; CX 508; see also JX 5 at UMG001523-001524; JX 26 at UMG000372; CX 383 at UMG003284.

315. There was no confusion between 3T1 and 3T2 prior to the release of 3T3. Stainer Dep. (JX 89) at 12-13, 19-20; Hidalgo Dep. (JX 88) at 22-24.

316. In 1994, PolyGram and Warner distinguished their respective Three Tenors products by slip case covers (a type of CD packaging), enhanced photo books, and product stickers. CX 272 at UMG00526; CX 288 at UMG006106; CX 296 at 3TEN00005912; CX 299 at 3TEN00005904; CX 300 at 3TEN00008946; see also Moore, Tr. 127-35.

317. Advertising campaigns for 3T1 and 3T2 could have differentiated these products from the new Three Tenors release. This was done in 1994 to distinguish 3T2 from 3T1. Stainer Dep. (JX 89) at 21; CX 249 at 3TEN00011254; CX 259 at 3TEN00011108.

318. Discounting of 3T1 and 3T2 also could have differentiated these products from the new Three Tenors release. Saintilan Dep. (JX 94) at 91-92.

319. Consumer confusion comes from the retail display of the albums. Saintilan Dep. (JX 94) at 91. If products are displayed appropriately, discounting need not lead to consumer confusion. Saintilan Dep. (JX 94) at 92.

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320. Record retailers display their products to avoid confusing consumers. Saintilan Dep. (JX 94) at 83; Caparro Dep. (CX 609) at 70-71.

321. PolyGram and Warner could have remedied any consumer confusion by requesting that retailers display 3T3 separately from 3T1 and 3T2. Saintilan Dep. (JX 94) at 84-85.

322. Warner could have secured commitments from retailers that 3T3 would be positioned prominently in the stores, and that 3T1 would not be positioned alongside 3T3. CX 612 (Stockum Rebuttal Expert Report) at P30; Stockum, Tr. 793-94; Wind Dep. (JX 91) at 81-86. Warner could have prevented any CD other than 3T3 from being placed in the special Eiffel Tower display it provided to retailers. O'Brien Dep. (JX 100) at 82. Record companies have been able to achieve exclusive space in retail stores. CX 249 at 3TEN00011253; Caparro Dep. (CX 609) at 66-67; Kopecky Dep. (CX 610) at 36-37, 64; Moore, Tr. 52, 261-62.

1. Respondents' evidence of consumer confusion

323. Respondents' expert witness, Dr. Yoram Wind, opined that it is theoretically possible that some consumers faced with too much variety may elect to postpone their purchase because they are not yet certain of the relative merits of the various products. Wind Dep. (JX 91) at 20-22, 131-33. However, the theory is premised upon "small studies" that are "not necessarily generalizable to the whole population." Wind Dep. (JX 91) at 25. Dr. Wind does not know how many, if any, consumers would find the offering of three albums so confusing that they buy none. Wind Dep. (JX 91) at 23.

D. Commercially Sound Marketing Strategy

324. Respondents' executives conclude that disappointing sales of 3T3 were probably attributable to the "tiring of the concept more than anything else." Cloeckert Dep. (JX 97) at 73-74; see also Stainer Dep. (JX 89) at 74; Hidalgo Dep. (JX 88) at

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91, 60-61; Saintilan Dep. (JX 94) at 35-37; Ordoover Dep. (JX 90) at 147.

325. Respondents' expert, Dr. Wind argues that the moratorium was "sound commercial strategy." Dr. Wind's opinion assumes that 3T1, 3T2, and 3T3 are a single product line. Wind Dep. (JX 91) at 78. Dr. Wind assumes that, when marketing a product line, the goal is to target the various products to different segments of the market. Wind Dep. (JX 91) at 77-78. However, Dr. Wind's essential assumption is inconsistent with the facts of the case - where Warner and PolyGram specifically retained their rights to exploit 3T1 and 3T2. F. 61-62.

326. Dr. Wind did not review the evidence in this case to determine if the moratorium was necessary, as opposed to merely theoretically or "plausibly" necessary. Wind Dep. (JX 91) at 10-11.

327. Dr. Wind has not studied, worked in, or consulted for the recorded music industry. Wind Dep. (JX 91) at 5.

328. Professor Catherine Moore, an expert in the marketing of recorded music products who testified at trial, explained that while it may be useful to market recorded music products by one artist together, this is not necessary because a new release must be given its own unique identity and form its own message to consumers. Moore, Tr. 139.

329. Unlike Dr. Wind, Professor Moore has substantial first hand experience in marketing music products. Based upon her demeanor and experience I found her testimony to be particularly credible. Professor Moore is the director of the music business program at New York University, and is also a professor in that program. The music business program is an academic program that trains students for careers in the music industry, particularly in marketing, advertising, and promotion. Professor Moore teaches courses that focus on marketing and pricing issues in the recorded music industry and consults in that field. In addition, Professor Moore has nearly 20 years of experience working in the

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recorded music industry in retail music stores, distribution companies and for labels. Moore, Tr. 8-18.

330. For these reasons, Dr. Wind's opinions about the "necessity" of a "commercially sound" strategy are given little weight.

XI. RISK OF RECURRENCE

331. It is not unusual for an artist to release material on more than one label. Moore, Tr. 85; Hoffman, Tr. 293-94; Gore Dep. (JX 87) at 68-69; Caparro Dep. (CX 609) at 76; Constant Dep. (JX 96) at 97; CX 604-D. Examples of artists that have switched from one label to another include Janet Jackson, Mariah Carey, Rod Stewart, Placido Domingo, Jose Carreras, Vladimir Horowitz, Daniel Barenboim and Leonard Bernstein. Moore, Tr. 85-87. Other examples identified by PolyGram witnesses include Terry Dexter and Fabulous (Hoffman, Tr. 293-94); Elton John and Willie Nelson (Caparro Dep. (CX 609) at 73-74); and Miles Davis, George Benson, Sarah Brightman, Peter White, and Keith Jarrett (Gore Dep. (JX 87) at 63-64, 68-69). Since it is common for an artist to record for more than one label over time, many artists have catalogue albums that appear on a label different from the label that releases the artist's new records. Moore, Tr. 85-89. When that occurs, the same incentives to enter into an agreement not to compete will exist that caused PolyGram and Warner to enter into the Three Tenors moratorium agreement.

332. It is common for one music company to "release" an exclusive artist to a competing company for purposes of a particular project. Moore, Tr. 39-40. The music company that receives the services of another company's exclusive artist, may reciprocate by releasing one of its exclusive artists for a future project. CX 513; CX 515; CX 516.

333. A music label may release an artist from his exclusive recording contract in return for a royalty on the artist's first album on his new label. When this occurs, the two competing labels have a shared financial interest in the success of a particular

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album. Hoffman, Tr. 357. Unless enjoined, Universal may seek a moratorium agreement to limit discounting or advertising of an artist's catalogue items on a competitor's label where it has obtained a release to have that artist perform for it.

334. Universal Music Group and Sony Music Entertainment have formed a joint venture to distribute music over the Internet. Universal, Sony, and other music companies will provide their music to the venture, known as "pressplay" on a non-exclusive basis. Accordingly, the music products marketed by the joint venture may also be marketed through traditional retail outlets. CX 553.

LEGAL ANALYSIS

I. SUMMARY OF FACTS

A. Joint Venture

The Three Tenors released three audio and video recordings from three concerts at three World Cup final games. F. 4-5. They first performed together at the Baths of Caracalla in Rome during the summer of 1990. F. 27. PolyGram acquired the rights to distribute audio and video recordings of the concert. F. 28. The 1990 Three Tenors album ("3T1") became the best selling classical record of all time. F. 29.

In 1994, the Three Tenors planned a second World Cup performance at Dodger Stadium in Los Angeles. F. 31. Concert promoter Tibor Rudas offered PolyGram a license for the rights to the concert. F. 32. They did not agree upon terms, and Rudas instead authorized Warner to distribute audio and video recordings derived from the 1994 Three Tenors concert ("3T2"). F. 33.

PolyGram reacted to Warner's new album. F. 210. In response to the release of 3T2, PolyGram advertised that 3T1 was the "original" Three Tenors recording - "unique and unrepeatabe," F.

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211, and marketed 3T1 at a discounted price, several dollars below the price of Warner's 3T2. F. 214-21.

Warner supported the release of 3T2 with a "high-power pop marketing effort," F. 202-04; CX 247, advertising the new album in newspapers and magazines, on television and billboards, and with elaborate in-store displays. F. 205. Warner offered retailers discounts on 3T2, and worked to secure prominent placement for the album within music stores. F. 206-07. A PolyGram executive described Warner's marketing of 3T2 as "the most impressive campaign I have seen in my days." Hidalgo Dep. (JX 88) at 46-47; F. 204. The 3T2 project was a commercial success for Warner. F. 222. Warner did not seek or secure a moratorium on competition. F. 200.

During 1996 and 1997, the Three Tenors participated in a worldwide tour. F. 224. Warner and PolyGram used the opportunity to drive sales of their respective Three Tenors products. F. 224. PolyGram offered 3T1 at discounted prices. F. 225. In addition, PolyGram released a World Tour Commemorative Edition of the 1990 concert, digitally re-mastered on a gold CD. F. 226. Warner's marketing campaign emphasized the virtues of 3T2 and downplayed the benefits of PolyGram's offering ("The digital re-mastering will be detectable by very few. . . . The so called 'Gold' disc is almost certainly not real gold."). F. 230.

Consumers benefitted from the price discounts, promotions, and product enhancements that flowed from this unrestrained competition. F. 232; CX 309. Both of the Three Tenors albums were among the best-selling classical recordings in the United States in 1994, 1995, 1996, and 1997. F. 234.

B. Collaboration on 3T3

During 1996, Tibor Rudas approached PolyGram and Warner separately to discuss the next Three Tenors project, a huge open-air concert in front of the Eiffel Tower to coincide with the World Cup finals in Paris in July 1998. F. 51. Both music companies

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were interested in acquiring the right to distribute the 3T3 products. F. 52-54.

In the spring of 1997, the Chairman of Atlantic Recording Corp. (a Warner subsidiary based in the U.S.) met with his counterpart at PolyGram "to ask that PolyGram allow Luciano Pavarotti to record the project for [Warner]." n3 F. 55. PolyGram responded with an offer of its own: Warner and PolyGram should share financial and operational responsibility, profits, and losses for the 1998 Three Tenors project. F. 56.

n3 Pavarotti was under exclusive contract with PolyGram. F. 55. In 1994, PolyGram had waived its exclusive rights, permitting Pavarotti to record 3T2 for Warner. F. 34. Warner was seeking a similar arrangement for 3T3. F. 55.

For \$ 18 million, Rudas licensed to Warner worldwide audio, video, and home television rights to the 1998 concert ("the 3T3 Rights"). F. 58. Warner sub-licensed to PolyGram the right to exploit the 3T3 Rights outside the United States. F. 59-60. Warner would distribute the new album and video in the United States, and PolyGram was responsible for the rest of the world. The parties also agreed:

- . that Warner and PolyGram would each receive 50 percent of the net profits and losses derived from the exploitation of the 3T3 Rights (as well as from the production of a Greatest Hits album and/or a Box Set incorporating the 1990, 1994, and 1998 concerts);
- . that PolyGram would reimburse Warner for 50 percent of the \$ 18 million advance paid to Rudas; and
- . that other expenses would be shared by Warner and PolyGram on a 50/50 basis.

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In negotiating the terms of the 1998 Three Tenors project, PolyGram and Warner and discussed the scope of a covenant not to compete. F. 61. The parties agreed that, for four years, neither would release a new Three Tenors album (except as part of the parties' collaboration). Warner insisted that the non-compete should not apply to the pre-existing Three Tenors albums. F. 62. The final collaboration agreement, dated December 19, 1997, provides that PolyGram and Warner shall each be free separately to exploit its older Three Tenors recordings. F. 62-63.

PolyGram and Warner recognized that the success of the new Three Tenors album was tied to the repertoire, F. 66, and wanted to be sure that the repertoire would be "distinctive," and that it would not repeat selections from the earlier Three Tenors recordings. F. 66. Rudas insisted that he and the artists should control the choice of songs. F. 67-68. PolyGram and Warner agreed. F. 69-72.

During 1998, PolyGram and Warner were concerned that their new Three Tenors album would not be as appealing as the 1990 and 1994 releases. F. 73. Various marketing strategies were considered. F. 74-78. Rudas assured that the album recorded in Paris would be new. F. 79-80. The record companies decided that the all new repertoire would be a key selling point. F. 81. PolyGram and Warner agreed that the packaging for 3T3 "must be as different as possible from the two previous releases." F. 78.

C. Moratorium Agreement

At a meeting of PolyGram and Warner representatives in New York in March 1998, PolyGram and Warner agreed not to discount or advertise 3T1 or 3T2 audio and video products in the weeks surrounding the release of the new recording. F. 90-96. They agreed that competition from the older Three Tenors products could reduce the sales and profitability of the new Three Tenors release. F. 268-73.

In April 1998, PolyGram instructed its opcos n4 that, pursuant to an agreement with Warner, aggressive marketing campaigns in

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support of 3T1 should terminate by the end of July. F. 107. Paul Saintilan (Senior Marketing Director, PolyGram) notified Warner of PolyGram's actions. F. 108-13. Later, PolyGram became concerned that the moratorium would not be implemented by Warner. F. 118-21, 126-27. PolyGram instructed its opcos that if, following the release of 3T3, Warner was discovered discounting 3T2 in a particular market, then the PolyGram opco was free to retaliate by discounting and promoting 3T1. F. 128-29.

n4 Both PolyGram and Warner distribute their products through a network of affiliated operating companies responsible for sales within a particular country or region. F. 23.

D. Repertoire for the 1998 Concert

In mid-June 1998, Rudas informed PolyGram and Warner of the intended repertoire for the upcoming Three Tenors concert. F. 133. The repertoire would include several compositions that were also included on 3T1 and/or 3T2. F. 133-34. PolyGram and Warner expressed to Rudas their dissatisfaction with the intended repertoire. F. 135.

E. Reaffirmance

On June 25, 1998, Anthony O'Brien (Warner) and Paul Saintilan (PolyGram) discussed by telephone their mutual desire to re-enforce the moratorium. F. 137-38. Once again they affirmed that, in the United States, 3T1 and 3T2 would not be discounted or advertised in the weeks following the release of 3T3 (scheduled for August 10, 1998). F. 138. O'Brien assured Saintilan that he would speak with other Warner executives about implementing the moratorium on a worldwide basis as well. F. 139.

On July 2 and July 10, 1998, Saintilan (PolyGram) provided O'Brien (Warner) with letters clarifying the terms of the moratorium, and seeking assurance that Warner would comply in all markets. F. 141-47. O'Brien conferred with executives from

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Warner's international distribution operation and secured their assent to the scheme. F. 148-49. Thereafter, O'Brien notified Saintilan that Warner would adhere to the moratorium on a worldwide basis. F. 150. In mid-July 1998, PolyGram and Warner issued written directives to their respective operating companies instructing that all discounting, advertising, and promotion of 3T1/3T2 was prohibited from August 1, 1998 through October 15, 1998. F. 148-49, 152-53.

F. Intervention of Attorneys

In late July 1998, after the Paris concert but prior to the release of 3T3, lawyers for PolyGram and Warner became involved with the moratorium issue. Paul Saintilan forwarded to PolyGram's General Counsel his documents relating to the Three Tenors moratorium - and then proceeded to "delete" such documents from his files. CX 459. On July 30, 1998, Saintilan wrote to PolyGram operating companies denying an agreement between PolyGram and Warner to restrict competition. F. 156-57.

Attorneys for the two record companies reviewed a draft letter from O'Brien (Warner) to Saintilan (PolyGram) purporting to reject the moratorium agreement for non-U.S. markets. F. 160-62. On August 10, 1998, O'Brien signed the letter and forwarded it to Saintilan. F. 161. Shortly thereafter, O'Brien telephoned Saintilan. O'Brien informed Saintilan that he (O'Brien) had been requested by counsel to send the August 10 letter. O'Brien further informed Saintilan that the Warner still intended fully to comply with the moratorium agreement on a worldwide basis. F. 163. O'Brien's understanding was that PolyGram likewise intended to comply with the moratorium agreement. F. 164.

G. Compliance

Warner and PolyGram complied with the moratorium agreement in the United States. F. 170-75. Between August 1, 1998 and October 15, 1998, neither Warner nor PolyGram discounted its respective catalogue Three Tenors products in the United States. F. 171, 173-74. Between August 1, 1998 and

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October 15, 1998, neither Warner nor PolyGram funded advertising for 3T1/3T2 in the United States. F. 172.

Both Warner and PolyGram substantially complied with the moratorium agreement outside of the United States as well. F. 177-81.

By memo dated October 26, 1998, Warner notified its operating companies that the moratorium on discounting older Three Tenors products was no longer in effect. CX 463. With the expiration of the moratorium agreement, Warner anticipated that PolyGram would "now discount [3T1] heavily." CX 462.

II. LEGAL DISCUSSION

A. Joint Venture

To encourage new output, the rules for evaluating collaboration by competitors are generally more lenient for joint ventures. n5 Firms may lack capital, labor or technology required to compete effectively in a new business, and case law has favored such collaboration by lowering the antitrust barriers to coordination which plausibly would generate procompetitive benefits. n6 Joint ventures are typically analyzed under the rule of reason. n7 A separate agreement connected to a joint venture will also be evaluated under the rule of reason where the agreement restraining competition is ancillary to the main purpose of the venture and "reasonably adapted and limited to the necessary protection of a party in carrying out of such purpose" *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 283 (6th Cir. 1897), *aff'd*, 175 U.S. 211 (1899) (Taft, J.). n8

n5 *In re Brunswick Corp.*, 94 F.T.C. 1174, 1265 (1979); *aff'd sub. nom. Yamaha Motor Corp. v. FTC*, 657 F.2d 971 (8th Cir. 1981).

n6 Thomas A. Piraino, Jr., *A Proposed Antitrust Approach to Collaborations Among Competitors*, 86 Iowa L. Rev. 1137, 1139 (2001).

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n7 Id. Joint ventures have no immunity from the antitrust laws, however. *NCAA v. Bd. of Regents*, 468 U.S. 85, 113 (1984). The rule of reason may involve only a quick look at justifications before condemning a naked restriction on price or output. *Chicago Prof'l. Sports Ltd. Partnership v. NBA*, 961 F.2d 667, 674 (7th Cir. 1992).

n8 Under the ancillary restraint doctrine "some agreements which restrain competition may be valid if they are . . . necessary to make that transaction effective." *Los Angeles Mem'l Coliseum Comm'n v. NFL*, 726 F.2d 1381, 1395 (9th Cir. 1984) (quoting Robert H. Bork, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, 74 *Yale L.J.* 775, 797-98 (1965)).

B. Ancillary Restraint Doctrine

A joint venture involves contractual undertakings by the parents. Some agreements, such as providing equipment, management, or capital, are central to the joint venture's operation and purpose. Other commitments not intrinsic to the venture may be given to reassure parents that some collateral event harmful to the venture does not occur. If the collateral agreement is necessary to make the joint venture work, and no broader than necessary, it will be ancillary to the venture and must be analyzed under the rule of reason. In *re Brunswick*, 94 F.T.C. at 1275 (citations omitted) described the ancillary doctrine:

Certain reductions in competition between the parents are an inevitable consequence of a joint venture agreement. For example, it is to be expected that the joint venturers will put their venture-related business into the venture and "not compete with their progeny." The Supreme Court has recognized that these limited reductions in competition are often necessary to make a joint venture operate efficiently, and therefore may escape the strict application of per se rules.

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But such agreements, to be legitimately ancillary to a joint venture, must be limited to those inevitably arising out of dealings between partners, or necessary (and of no broader scope than necessary) to make the joint venture work.

To be ancillary to the joint venture, then, a collateral restraint must be an integral part of the venture, or reasonably necessary to make it work. In *Brunswick*, one of the collateral agreements found to violate Section 5 foreclosed Yamaha, one of the joint venturers, from selling its own brand in the United States in competition with the joint venture product. *Id.* at 1276. Yamaha had been buying and reselling outboard motors in the United States under its label, and this business was not included in the assets placed into the joint venture, and was not integral to it. Here, similarly, 3T1 and 3T2 were not placed into the joint venture.

Complaint Counsel argue that the moratorium agreement, to be ancillary, must be essential to the purpose of the joint venture. Respondents argue that it need only be plausibly connected to the venture. *Brunswick* states the law needed to answer this question. To be ancillary, the restriction is "limited to those inevitably arising out of dealings between the partners, or necessary (and of no broader scope than necessary) to make the joint venture work." *Id.* at 1275. In *Polk Bros, Inc. v. Forest City Enters.*, 776 F.2d 185 (7th Cir. 1985), Respondents' strongest case, the restraint was held ancillary because it "may promote the success of" the venture; but the court further held that "the covenant allocating items between the retailers played an important role in inducing the two retailers to cooperate" and Polk "would not have entered into this arrangement . . . unless it had received assurances that [Forest City] would not compete with it. . . . The agreement not to compete was an integral part of the lease and land sale." 776 F.2d at 189-90 (emphasis added). Thus, to be ancillary, the restraint must be an integral part of the venture or reasonably necessary to its promotion. n9

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n9 Cases in which suspect restraints were upheld involved restraints on products created by, not outside of, the joint venture. *Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 23-24 (1979) ("BMI") (price restraint affected blanket license that was the product of the joint venture; participants were free to separately license and price their individual works); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 214 (D.C. Cir. 1986) (restrictions concerned ventures' use of joint venture assets); *Polk Bros.*, 776 F.2d at 189-90 (restraint applicable to sales from jointly constructed facility only; ventures remained free to increase output from separately operated facilities). Unlike these cases, the restraint here was not necessary for the creation of the product of the joint venture nor was it a restraint on the product created by the joint venture.

The moratorium agreement was not necessary for the creation of 3T3. The negotiators of the 3T3 joint venture did not have it in their minds while creating the joint venture and in fact specifically agreed that they could continue to exploit 3T1 and 3T2 during the sale of the venture product 3T3. F. 62, 262. The belated moratorium may have been intended to support the introduction of 3T3, but it was created months after the joint venture agreement. F. 263. n10 Further, Warner successfully introduced 3T2 in 1994 in the face of serious competition, with discounts and advertising, by PolyGram's 3T1. F. 200-23. Unless Respondents meet their burden of showing an efficiency justification, the moratorium agreement therefore would not be ancillary to the joint venture.

n10 Just as in *NCAA*, involving a lawful joint venture to organize college athletic teams, the agreement at issue was not a legitimate ancillary agreement. *NCAA*, 468 U.S. at 113; see also *Law v. NCAA*, 134 F.3d 1010, 1018 n.18 (10th Cir. 1998). In both *NCAA* cases, the restraints may have been supportive of the lawful joint venture but were not integral to it and were broader than necessary to accomplish the purpose. Although *NCAA v. Regent* held

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the television plan as an unreasonable restraint violating the Sherman Act, the Court could well have found that the plan was supportive of the legitimate joint venture. The television plan there promoted the balance of teams, one of NCAA's essential lawful objectives. *Gen'l Leaseways Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 595 (7th Cir. 1984) (Posner, J.). However, NCAA held that the television plan was not a legitimate joint venture agreement because, unlike BMI, it did not act as a joint sales agent. The selection of the individual games and the negotiation of particular agreements were left to the networks and the individual schools. The television plan did not eliminate individual sales of broadcasts, since these still occurred, albeit subject to the fixed prices and output limitations, just as in *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982). Similarly, the moratorium agreement here could support the lawful joint venture but still violate Section 5 because it was not integral to the venture nor necessary to market the product. *NCAA*, 468 U.S. at 114. To prove that the moratorium was integral to the venture, Respondents rely on the testimony of Mr. O'Brien that had he known that PolyGram was going to discount 3T1 during the introduction of 3T3 he would not have entered into the joint venture. Tr. at 514-15. The weight of such after the fact reasoning to show intent is generally suspect. *Gen'l Leaseways*, 744 F.2d at 595-96. Since the joint venture agreement specifies that Warner and PolyGram shall be free separately to exploit [e.g., sell at a discount] its older Three Tenors recordings, F. 62-63, this testimony seems to be questionable.

C. Burden of Proof

Complaint counsel argue that the moratorium agreement is price fixing and reduction in output presumptively anticompetitive, requiring the use of the per se or quick look analysis and shifting the burden to respondents to demonstrate a countervailing efficiency sufficient to overcome the presumption. Complaint counsel further argue that the

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respondents' proffered efficiency justifications are implausible or invalid. Thus, complaint counsel urges a finding of a violation of Section 5 of the FTC Act.

Respondents argue that the moratorium agreement was ancillary to the joint venture, since it plausibly supports the main purpose of the joint venture; that the rule of reason applies to ancillary restraints; that complaint counsel failed to prove competitive injury from the moratorium agreement, relying instead on a presumption of anticompetitive effects from the nature of the agreement; and that the lack of evidence of harmful market effects under the rule of reason requires dismissal of the case.

1. Per Se Rule

The moratorium agreement restricted competition in advertising and the price of 3T1 and 3T2, which were not products produced and sold by the joint venture. F.264-67. n11 It was not ancillary to the joint venture and appears to be a naked agreement to fix prices and restrict output. The moratorium agreement could, therefore, be analyzed as a naked agreement n12 violating Section 5 under the per se rule. n13

n11 The Warner and PolyGram joint venture agreement did provide that a selection of hits and box products taken from 3T1 and 3T2 might be sold through the joint venture starting in 1999. During the term of the moratorium agreement, August 1 to October 15, 1998, F. 149, the joint venture sold only 3T3. Speculative future joint activity cannot justify a price-fixing agreement in effect during 1998. Herbert Hovenkamp, XI Antitrust Law P1906b at 212 (1998), ("The principle reason for rejecting defenses that a restraint is competitive in the long run is that proof is nearly always highly speculative and the defense could be asserted so often that it would effectively undermine a large proportion of instances properly subject to per se disposition.").

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n12 Law analyzed the agreement on coaches' salaries under the rule of reason because college sports is an industry where some horizontal agreements among NCAA members are necessary if there is to be a product at all. 134 F.3d at 1019. Respondent did not prove that the music industry requires joint ventures in order to increase output.

n13 Price fixing agreements lack redeeming virtue and are conclusively presumed to be unreasonable. Nat'l Soc'y of Prof'l Engineers v. United States., 435 U.S. 679, 692 (1978) ("NSPE"); Maricopa, 457 U.S. at 344.

2. Rule of Reason

If the case is analyzed under the rule of reason: n14 (1) complaint counsel bears the initial burden of showing that an agreement had a substantially adverse effect on competition; (2) if complaint counsel meets this burden, the burden shifts to respondent to come forward with evidence of procompetitive virtues of the alleged wrongful conduct; and (3) if respondents are able to demonstrate procompetitive effects, complaint counsel then must prove that the challenged conduct is not reasonably necessary to achieve the legitimate objectives or that those objectives can be achieved in a substantially less restrictive manner. Ultimately, if those steps are met, the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable. n15

n14 Judge Posner felt it was prudent to use both rules in Gen'l Leaseways, 744 F.2d at 569, since "it is possible we are wrong in holding this case is governed by the per se rule. . . ."

n15 The sequence of shifting of burdens is described in Law. 134 F.3d at 1019; see also United States v. Brown University, 5 F.3d 658, 669 (3rd Cir. 1993).

Since it was unnecessary and not integral to the joint venture, the moratorium agreement appears to be one that would always or

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almost always tend to restrict competition and decrease output. *BMI*, 442 U.S. at 19-20. The elimination of competition is apparent on a quick look. A restraint on competition between parents and the joint venture may be a naked agreement, subject to quick look analysis under the rule of reason. *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999) ("CDA"); *Law*, 134 F.3d at 1020. If the anticompetitive effects of price fixing are obvious the burden of proceeding switches. *NSPE*, 435 U.S. at 692. n16

n16 A naked, effective restraint on market price or volume can establish anticompetitive effect under a truncated rule of reason analysis. *Chicago Prof'l Sports*, 961 F.2d at 674; see also *General Leaseways*, 774 F.2d at 595.

Respondents therefore would have the burden of showing that the procompetitive benefits of the restraint justify the anticompetitive effects. *Law*, 134 F.3d at 1021. Justifications offered under the rule or reason may be considered only to the extent that they tend to show that, on balance, the challenged restraint enhances competition. *NCAA*, 468 U.S. at 104.

D. Competitive Effects

Some restraints almost always tend to raise price or reduce output; the presumptively anticompetitive effect of such an agreement is "intuitively obvious." *CDA*, 526 U.S. at 781; *NCAA*, 468 U.S. at 110. Where anticompetitive effects are presumed, the burden shifts to the respondents to demonstrate a countervailing efficiency sufficient to overcome the presumption. *CDA*, 526 U.S. at 770-71 (1999); *NCAA*, 468 U.S. at 113. This shift occurs in the "abbreviated or 'quick-look' analysis under the rule of reason." *CDA*, 526 U.S. at 770. n17 Where restraints raise obvious potential anticompetitive effects, the merits of the proffered efficiency justifications should be considered in advance of conducting a market analysis. Presumptively anticompetitive restraints may be condemned without assessing market power or examining actual anticompetitive effects. *Id.* at 779; *Brown University*, 5 F.3d at 673. "The absence of proof of market power does not justify a naked restriction on price or

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output This naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis." NCAA, 468 U.S. at 109-10. The Court rejected the NCAA's efficiency justifications, finding that they were plausible but unsupported by the evidence (i.e., invalid). n18

n17 See BMI, 441 U.S. at 30; NCAA, 468 U.S. at 110; F.T.C. v. Indiana Fed'n of Dentists, 476 U.S. 447, 459 (1986) ("IFD"); Continental Airlines v. United Airlines, 277 F.3d 499, 508-510 (4th Cir. 2002); Law, 134 F.3d at 1019-1020; Brown University, 5 F.3d at 669; Chicago Prof'l Sports, 961 F.2d at 674; General Leaseways, 744 F.2d at 595; In re: Detroit Auto Dealers Assoc., 111 F.T.C. 417, 493 (1989); In re: Massachusetts Bd. Of Registration in Optometry, 110 F.T.C. 549, 603-604 (1988).

n18 A naked restraint on price and output is unaccompanied by new production or products; an ancillary restraint is part of a larger endeavor whose success it promotes. Polk Bros., 776 F.2d at 188-89. A naked restraint may be found unlawful even though contained in elaborate joint ventures that were not being challenged and were socially beneficial. For example, while the NCAA is a socially beneficial athletic venture involving colleges and universities, both its rule limiting televised football games and the rule fixing maximum coaches salaries were properly characterized by the court as 'naked' restraints on price or output. NCAA 468 U.S. at 113-14; Law, 134 F.3d at 1018 n.10.

The issue here, then is whether the agreements between PolyGram and Warner to forgo discounting and advertising fall within a category of restraints that is likely, absent an efficiency justification, to lead to higher prices or reduced output. n19 The assessment of whether a category of restraints is inherently likely to be anticompetitive should be guided by common sense, legal precedent, and economic theory and research. n20

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n19 BMI, 441 U.S. at 19-20; IFD, 476 U.S. at 459; NCAA, 468 U.S. at 109-110; Brown University, 5 F.3d at 669 (abbreviated antitrust analysis appropriate where "'no elaborate industry analysis is required to demonstrate the anticompetitive character' of an inherently suspect restraint"); Detroit Auto Dealers Assoc., 111 F.T.C. at 498; Mass. Board, 110 F.T.C. at 604 ("First, we ask whether the restraint is 'inherently suspect.' In other words, is the practice the kind that appears likely, absent an efficiency justification, to 'restrict competition and decrease output'").

n20 See CDA, 526 U.S. at 781; NCAA, 468 U.S. at 103; Detroit Auto Dealers' Assoc., 111 F.T.C. at 496.

1. Agreement on price

The agreement between PolyGram and Warner not to discount 3T1 and 3T2 is price fixing, n21 and subject the abbreviated review. n22 An agreement between competitors to fix minimum prices threatens the efficient functioning of a market economy. FTC v. Ticor Title Ins. Co., 504 U.S. 621, 639 (1992); FTC v. Super. Ct. Trial Lawyers Ass'n, 493 U.S. 411, 435 n.16 (1990) ("SCTLA"); NCAA, 468 U.S. at 100.

n21 F. 235. Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643, 648 (1980).

n22 BMI, 441 U.S. at 1; NCAA, 468 U.S. at 100; NSPE, 435 U.S. at 692.

PolyGram and Warner often find it necessary to offer discounts to retailers in order to increase sales levels; this is true of both new releases and older (or catalogue) recordings. F. 239. During 1994, PolyGram responded to the release of 3T2 by aggressively reducing the price of 3T1 in many markets--to the benefit of consumers. F. 214-21. And again in 1998, many PolyGram and Warner operating companies determined that the best way to capitalize upon the public's revived interest in the Three Tenors was by reducing the price of these products

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(coupled with aggressive advertising campaigns). F. 103-05, 115-18.

An agreement to forgo discounting has an obvious anticompetitive potential. And it is no defense that the competitive injury here was small. That the restrictions were relatively small in scope and is limited in time provides no escape from liability. "A court applying the Rule of Reason asks whether a practice produces net benefits for consumers; it is no answer to say that a loss is 'reasonably small.'" *Chicago Prof'l Sports*, 960 F.2d at 674; *SCTLA*, 493 U.S. at 434-35.

2. Agreement on advertising

The agreement between PolyGram and Warner to forgo all advertising is also presumptively anticompetitive. ⁿ²³ CDA expressed a more permissive view toward limited advertising restraints in a professional services market. However, the Court indicated that a complete ban on truthful, non-deceptive advertising--especially in an ordinary commercial market--should continue to be viewed harshly. *CDA*, 526 U.S. at 773.

ⁿ²³ See *Blackburn v. Sweeney*, 53 F.3d 825, 827 (7th Cir. 1995); *United States v. Gasoline Retailers Ass'n*, 285 F.2d 688, 691 (7th Cir. 1961); *Federal Prescription Serv., Inc. v. American Pharm. Ass'n*, 484 F. Supp. 1195, 1207 (D.D.C. 1980), *aff'd in part rev'd on other grounds in part*, 663 F.2d 253 (D.C. Cir. 1981); *Massachusetts Bd.*, 110 F.T.C. at 606-608.

Antitrust law's hostility to advertising bans is supported by economic theory and empirical research. Information disseminated through advertising serves to educate consumers about the availability of alternatives, quality differences among competing products, sales locations, means of purchase, and pricing. This information assists consumers to find their preferred products at low prices, and thus serves to promote competition. *F. 244-45*; see *CDA*, 526 U.S. at 773 n.10; *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977).

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Advertising restrictions result in consumers paying higher prices. F. 246. Even a short-lived restraint on advertising can have a significant effect on consumers. Dr. Stockum described a study of the New York newspaper strike. n24 In New York, newspapers are important for grocery store advertising. After only a single week without newspapers, supermarket prices increased because of the restriction on advertising. Absent an efficiency justification, Respondents' agreement not to advertise or promote catalogue Three Tenors albums is also likely to be anticompetitive. F. 248.

n24 F. 246-47; Stockum, Tr. 599-600.

Advertising has proven to be an important competitive tool in the marketing of Three Tenors products. In 1994, PolyGram used advertising to teach consumers that 3T1, the "original" Three Tenors recording, was still the best performance, still widely available, and indeed often available at a discounted price. F. 210-13, 253. Warner used advertising in its effort to create a distinct identity for 3T2, and to suggest to consumers that the newer release was the superior product. F. 201-09, 254.

During 1998, PolyGram and Warner operating companies wished to offer their older Three Tenors recordings at a discount. Discounting was coupled with an aggressive advertising campaign. F. 103-05, 115-18, 255-58. Warner forecast that by advertising the discount on the wholesale price of 3T2, the company sales could increase by 170 percent. F. 256. Advertising of recorded music can create additional demand, and hence an environment in which discounting by record companies is more likely to occur. F. 259. Upon the release of 3T3 in 1998, PolyGram and Warner aggressively advertised it in every available media. F. 168. The record companies intended that their advertising ban would conceal the availability of better value Three Tenors recordings, and that consumers would instead purchase the higher margin 3T3 release. F. 269. The potential anticompetitive effect of this strategy is obvious.

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E. Efficiency Defenses**1. Must be plausible and valid**

Since the Three Tenors moratorium involved presumptively anticompetitive restraints, Respondents must demonstrate a plausible and valid efficiency justification. CDA, 526 U.S. at 771; NCAA, 468 U.S. at 113. n25 Respondents must show that the moratorium was necessary in order to promote competition and benefit consumers. BMI, 441 U.S. at 23; NCAA, 468 U.S. at 114. n26

n25 Respondents put into evidence the reports of its experts Dr. Yoram Wind and Dr. Janusz Ordover. Expert reports are not as reliable as expert testimony at trial. *Tokio Marine and Fire Ins. Co. v. Norfolk & Western Rwy. Co.*, 1999 U.S. App. LEXIS 476, *10 (4th Cir. 1999); *Engerbretsen v. Fairchild Aircraft Corp.*, 21 F.3d 721, 729 (6th Cir. 1994). The report is not submitted under oath. There is no basis to evaluate the expert's qualifications or credibility. *EPIS, Inc. v. Fidelity and Guar. Life Ins. Co.*, 156 F. Supp. 2d 1116, 1124 (N.D. Cal. 2001). The witness has not been judicially designated as an expert. The witness has not been subject at trial to cross-examination. *Weil v. Long Island Sav. Bank*, 2001 U.S. Dist. LEXIS 22915, *10-11 (E.D.N.Y. 2001).

In preparing his report, Dr. Wind reviewed no documents from the files of Warner or deposition testimony of any individual responsible for marketing 3T3 in the United States; or any Warner employee. F. 327. Dr. Wind discusses whether the moratorium is plausibly pro-competitive, but he does not evaluate whether the restraints were actually necessary to achieve some efficiency in the United States. Wind Dep. (JX 91) at 10-11. Dr. Ordover's report rejects the basic premises of modern antitrust analysis. According to Dr. Ordover, if a restraint is adopted in the context of a non-sham joint venture, then the restraint should be considered to be "reasonably necessary," Ordover

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Dep. (JX 90) at 50, and analyzed under the full rule of reason. Ordover Dep. (JX 90) at 44 ("I would say that a--a quick look of restraints would be best left for those joint ventures that are a sham."). According to Dr. Ordover, there is no threshold requirement to consider the validity of the efficiency argument, Ordover Dep. (JX 90) at 213, and no need to consider the availability of less restrictive alternatives. Ordover Dep. (JX 90) at 77. This is inconsistent with the antitrust case law governing abbreviated rule of reason, *NCAA*, 469 U.S. 85; *Law*, 134 F.3d 1010; *Chicago Prof'l Sports*, 961 F.2d 667; *General Leaseways*, 744 F.2d 588. Because they are unsupported by live testimony, untested by cross-examination, detached from the evidence adduced in this case, and inconsistent with the case law, the reports of Drs. Wind and Ordover have little evidentiary value.

n26 An efficiency argument is implausible (insufficient on its face) where, for example, it is pretextual, *Eastman Kodak Co. v. Image Technical Servs. Inc.*, 504 U.S. 451, 461 (1992), inapposite to the factual circumstances presented, *Law*, 134 F.3d at 1022, or where the argument is premised upon the claim that competition is unworkable or undesirable. *IFD*, 476 U.S. at 463; *NCAA*, 468 U.S. at 116-7; *NSPE*, 435 U.S. at 696. An efficiency justification should be rejected as invalid where, inter alia, it is speculative or unproven, *IFD*, 476 U.S. at 463; *Chicago Prof'l Sports*, 961 F.2d at 674-76, where the argument sweeps too broadly, *IFD*, 476 U.S. at 463; *Catalano*, 446 U.S. at 649-50; *NSPE*, 435 U.S. at 696; *Mass. Board*, 110 F.T.C. at 607-08, where there is a less restrictive alternative, *NCAA*, 468 U.S. at 114; *Maricopa County Med. Soc'y*, 457 U.S. at 351-52; *NSPE*, 435 U.S. at 696; *Chicago Prof'l Sports*, 961 F.2d at 674-76; *Mass. Board*, 110 F.T.C. at 607-08, or where the restraint is not an effective remedy for the competitive problem that it purports to address. *NCAA*, 468 at 116, 119; *Law*, 134 F.3d at 1022-24.

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Respondents must demonstrate that the moratorium did in fact promote the efficiency of the PolyGram/Warner collaboration. In re: Indiana Fed. of Dentists, 101 F.T.C. 57, 175 (1983), vacated, 745 F.2d 1124 (7th Cir. 1984), rev'd, 476 U.S. 447 (1986); CDA, 526 U.S. at 775 n. 12. n27 Respondents have the burden of showing "empirical evidence of procompetitive effects" in the context of a "quick look" analysis. CDA, 526 U.S. at 775 n.12. n28 The case can be resolved on an abbreviated analysis of the proffered efficiency justifications without an examination of market power or actual anticompetitive effects. n29

n27 See also Timothy J. Muris, *The Federal Trade Commission and the Rule of Reason: In Defense of Massachusetts Board*, 66 *Antitrust L.J.* 773, 778-79 (1998) ("Compared to the plausibility stage inquiry, the court must delve more deeply into the factual assertions of the parties to determine whether (1) the claimed efficiency benefits are real, and (2) the restraint is reasonably necessary to achieve them. If a proffered explanation fails on either count, then the court should declare the challenged restraint unlawful under the abbreviated rule of reason.").

n28 CDA, 526 U.S. at 779-81.

n29 *Continental Airlines*, 277 F.3d at 508.

The parties' motivation for the moratorium was to shield 3T3 from competition. F. 268-75. But even if the parties harbored a good faith belief that the moratorium was necessary and procompetitive, this would not establish the validity of any efficiency justification. *NCAA*, 468 U.S. at 101 n.23. Respondents' assertion that the moratorium would assist PolyGram and Warner to recoup their \$ 18 million investment is not a procompetitive (i.e., pro-consumer) justification for the Three Tenors moratorium. *Chicago Prof'l Sports v. NBA*, 754 F. Supp. 1336, 1359 (N.D. Ill. 1991), aff'd, 961 F.2d 667 (7th Cir. 1992). n30 It is not a defense under the FTC Act. *SCTLA*, 493 U.S. at 422.

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n30 See also *Law*, 134 F.3d at 1023; *Delaware & Hudson Ry. Co. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990).

Respondents contend that the Three Tenors moratorium was adopted in response to the risk that certain European operating companies would free ride on the promotional opportunity created by the Paris concert. Respondents cannot justify the agreement to restrain competition in the marketing of Three Tenors products in the United States with the claim that the moratorium was necessary for the efficient marketing of 3T3 in Europe. *Law v. NCAA*, 902 F. Supp. 1394, 1406 (D. Kan. 1995), *aff'd*, 134 F.3d 1010 (10th Cir. 1998); *Sullivan v. National Football League*, 34 F.3d 1091, 1112 (1st Cir. 1994); *RSR Corp. v. FTC*, 602 F.2d 1317, 1325 (9th Cir. 1979).

2. The moratorium must be necessary

In December 1997/January 1998, Polygram and Warner agreed to pay \$ 18 million to Rudas in exchange for the right to distribute audio and video recordings of the next Three Tenors concert. F. 58-59. The parties first agreed to the moratorium later, in March 1998. F. 92-94. The later moratorium agreement cannot be deemed necessary for the earlier agreement to collaborate. F. 263.

Respondents stipulate that the Three Tenors' moratorium was not necessary to the formation of the joint venture between PolyGram and Warner. F. 262. It also was not necessary for the production of the Paris concert, for the creation of 3T3, or to assure the distribution of 3T3 in the United States. PolyGram and Warner were committed to these activities well before discussions of the moratorium even commenced. F. 263-64. The challenged restraints were not necessary to procure any of the activities. n31

n31 *Blackburn*, 53 F.3d at 828 (allocation of territories was not ancillary to agreement to dissolve law partnership where restraint was adopted after the termination of the partnership); *Polk Bros.*, 776 F.2d at 189.

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3. Free-riding

Respondents argue that without the moratorium agreement, promotional investments by PolyGram and Warner intended to benefit sales of 3T3 in Europe may instead have led some consumers in Europe to purchase at a lower price 3T1 (distributed by PolyGram) or 3T2 (distributed by Warner).ⁿ³² To be sufficient to justify an agreement to fix prices and forgo all advertising in the United States, Respondents must show that: (i) absent the challenged restraints, free-riding is likely to have the effect of eliminating some valued service from the marketplace; (ii) there was no reasonable means by which the competitor that benefits from the valued service (the alleged free rider) could have compensated the firm that was providing such service; and (iii) there were no less restrictive alternatives. *Toys "R" Us, Inc.*, 126 F.T.C. 415, 600-07 (1998) ("TRU"), *aff'd*, 221 F.3d 928 (7th Cir. 2000).

ⁿ³² Respondents' Trial Brief at 13.

It is common for advertising to benefit a competitor different from the firm that funded the advertising. CX 612 (Stockum Rebuttal Report) at P17. The prospect of free-riding does not, however, lead sellers of consumer products to abandon all advertising.ⁿ³³ Instead, sellers generally respond to this challenge by using advertising to create a distinct identity for the target product.ⁿ³⁴

ⁿ³³ Wind Dep. (JX 91) at 128-29.

ⁿ³⁴ Ordover Dep. (JX 90) at 199; CX 612 (Stockum Rebuttal Expert Report) at P17.

Within the recorded music industry, free-riding is commonplace. Advertising intended to benefit one album often leads to sales of competing albums. F. 280.ⁿ³⁵ Warner introduced 3T2 during 1994. Warner anticipated competition from PolyGram (3T1). F. 200, 202. But Warner did not forgo all

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advertising (and Warner did not seek a moratorium with its rival). F. 200-09. Instead, Warner devised an aggressive marketing campaign aimed at distinguishing 3T2 and convincing consumers that 3T2 was preferable to 3T1. F. 203. Warner's marketing campaign for 3T2 was a success; the project was profitable; and four years later Warner was anxious to acquire distribution rights to 3T3--initially without the participation of PolyGram. F. 52, 222-23.

n35 Cloeckaert Dep. (JX 97) at 46; F. 281; RX 716 (Ordover Expert Report) at P36; Ordover Dep. (JX 90) at 130.

Advertising for one product often will benefit rival products, however more than just lost sales is required in order to justify a resort to price fixing--or else price-fixing agreements would be the rule rather than the exception. Herbet Hovenkamp, XII Antitrust Law P2032b at 184 (1999) ("free-riding is ubiquitous in our society"). Respondents must show a danger that, because of free-riding and absent a restraint, advertising for 3T3 would have disappeared or have been substantially curtailed.

The evidence on this issue does not support Respondents' free-riding defense. Witnesses representing both Warner and PolyGram testified that 3T3 would have been aggressively and appropriately promoted without the moratorium, and indeed that the moratorium had no significant effect on the resources devoted to advertising and promoting 3T3. O'Brien, Tr. 448, 490; Saintilan Dep. (JX 94) at 88-89, 194-195. In June 1998, when it appeared to PolyGram that the Three Tenors moratorium would fall apart, PolyGram did not alter its marketing strategy or cut back on its advertising budget. PolyGram's only response was to notify its operating companies that if Warner were found selling 3T2 at discounted prices in any territory, then the local PolyGram operating company could respond by discounting 3T1. F. 129-30. n36

n36 Saintilan Dep. (JX 94) at 82.

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If there were a serious free-riding problem in connection with the marketing of 3T3, the problem existed in Europe but not the United States. Ordover Dep. (JX 90) at 36-37. Dr. Ordover calculated that the magnitude of sales diverted from 3T3 to 3T1 in the United States due to free-riding during the moratorium period (August - October 1998) would have been small (sales of less than \$ 86,000 per month). F. 294. Dr. Ordover was unable to conclude that free-riding in the United States would have had a significant impact on the venturers' incentives to advertise 3T3. Ordover Dep. (JX 90) at 158-59.

The Three Tenors moratorium agreement was not necessary to preserve incentives to advertise and promote 3T3 in the United States. Respondents' free-riding defense therefore fails. See TRU, 126 F.T.C. at 605.

Even assuming that there was a legitimate concern with free-riding here, there is also a solution: joint advertising arrangements. Where firms that share the benefits from advertising also share of the costs of such advertising, any free-riding problem is remedied. TRU, 126 F.T.C. at 602.

PolyGram and Warner decided to share the cost of promoting 3T3 in the United States, on a 50/50 basis. O'Brien, Tr. 419-20. n37 The ability of PolyGram and Warner to compensate one another for the value of the 3T3 advertising defeats the free-riding defense. Chicago Prof'l Sports, 961 F.2d at 675, and General Leaseways, 744 F.2d at 592. n38

n37 The license agreement between Warner and PolyGram provides that the two music companies shall each be entitled to 50 percent of the net profits and net losses derived from sales of 3T3 worldwide. Any advertising or marketing expenses incurred by either party are to be deducted from revenues for purposes of calculating net profits (losses). Given the financial structure of the venture, every dollar spent in the United States by Warner to promote 3T3 is partially reimbursed by

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PolyGram; fifty cents comes from each of the venturers. F. 301.

n38 See also *High Tech. Careers v. San Jose Mercury News*, 996 F.2d 987, 992 (9th Cir. 1993); *United States v. Microsoft Corp.*, 1998-2 Trade Cas. (CCH) P72, 261 at 82,682 (D.D.C. 1998); *TRU, Inc.*, 126 F.T.C. at 601.

Respondents contend that whereas PolyGram and Warner allocate the costs of advertising on a 50/50 basis, the division of benefits from 3T3 advertising may not be precisely equal. It is not important that compensation from one competitor to the other be exactly the right amount. It is sufficient that the cost-sharing mechanism "ensure[s] the continuation of the beneficial activity." *TRU*, 126 F.T.C. at 602.

Warner and PolyGram agreed to share the cost of advertising and promoting 3T3 upon terms satisfactory to them. This limited form of cooperation eliminates the free-riding problem and obviates the need for the parties to engage in price-fixing or to adopt an advertising ban. F. 300-05. The scope of the moratorium could also have been limited to Europe. F. 306. n39

n39 There is no evidence that, during the moratorium period, discounted copies of 3T1 and 3T2 would have been transshipped from the United States to Europe. Nor is there evidence that such transshipment would disrupt the marketing of 3T3 in the United States or anywhere else. F. 307-08.

In addition, any danger that advertising for 3T3 may have benefitted the older Three Tenors albums arose principally because 3T3 was not sufficiently different from 3T1 and 3T2. RX 617 (Ordovery Expert Report) PP16, 31. In 1994, Warner used the tools of marketing (e.g., packaging, advertising) to create a unique identity for 3T2, distinct from 3T1. F. 203-08. A similar strategy could have been pursued for 3T3 in 1998. n40

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n40 See JX 106 (Moore Rebuttal Expert Report) PP5-11; Moore, Tr. 123-35; Ordoover Dep. (JX 90) at 144.

4. Consumer confusion

Respondents argue that the moratorium helped eliminate the risk that some consumers would confuse the various Three Tenors albums and not purchase the new album that they intended to buy. Analogous challenges to consumer sovereignty were dismissed in IFD and NSPE, as "nothing less than a frontal assault on the basic policy of the Sherman Act." n41

n41 IFD, 476 U.S. at 463 (rejecting claim that providing x-rays to insurance companies will necessarily lead them to make unwise and dangerous choices); NSPE, 435 U.S. at 694 (rejecting claim that competitive bidding will necessarily lead to inferior engineering work).

There is no evidence that consumers were confused in selecting among the various Three Tenors albums--only that PolyGram marketing manager Paul Saintilan was "concerned" that confusion may arise. F. 312-13. This feeling was not based upon research, data, or observation. F. 312. It does not justify restraints on competitive activity. n42

n42 Absent the moratorium, discounting of 3T1 and 3T2 could have helped to differentiate these products from the new Three Tenors release. F. 318. Advertising campaigns on behalf of 3T1 and 3T2 could have emphasized the distinctive features of these albums (as was done in 1994). F. 317. The competitive activity squelched by the moratorium should dispel rather than foster consumer confusion. Cf. Law, 134 F.3d at 1024.

Confusion identified by Respondents could have been remedied though measures less restrictive than the moratorium. If the cover art for 3T3 resembled the cover art for 3T1 and 3T2, packaging for 3T3 could be made more distinct. F. 314. Music retailers have the incentive and ability to display their products in

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a manner that would not confuse their customers. F. 319-20. Warner could have worked with music retailers to ensure that 3T3 was displayed in a manner that consumers would not find confusing. F. 321-22.

To cure consumer confusion, a seller is not permitted to make its product appear unique by inducing a competitor to withdraw its competing products. n43 Confusing competition is preferred to the clarity offered by collusion. n44

n43 NCAA, 468 U.S. at 116-17.

n44 United States v. Western Electric Co., 583 F. Supp. 1257, 1260 (D.D.C. 1984).

The suppression of 3T1 and 3T2 was not necessary to the effective marketing of 3T3. In 1994, Warner marketed 3T2 effectively and successfully without suppressing 3T1. In 2000, Sony released the fourth Three Tenors album, consisting principally of Christmas songs. Sony marketed its Three Tenors album without seeking a moratorium on the marketing of previous Three Tenors albums. F. 197-99.

The real issue is not that consumers are confused by multiple Three Tenors products. Consumers are discerning. Given a choice between 3T3 and one of the older Three Tenors albums, some consumers may view a discounted 3T1 or 3T2 as the better value. F. 268-69. The safest way for PolyGram and Warner to maximize their profits on 3T3 was, therefore, to agree to maintain high prices on the older Three Tenors recordings.

That 3T3 was (in the eyes of the record companies and perhaps consumers) a disappointing product cannot justify an effort by the venturers to insulate this product from competition. F. 324. A similar argument was rejected in NCAA. The NCAA joint venture argued that a restriction on the telecast of college football games was necessary in order to protect live attendance at games. Such a strategy, the Supreme Court explained, would diminish rather than enhance consumer welfare: "By seeking to

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insulate live ticket sales from the full spectrum of competition because of its assumption that the product itself is insufficiently attractive to consumers, petitioner forwards a justification that is inconsistent with the basic policy of the Sherman Act." NCAA, 468 U.S. at 116-117.

5. The moratorium as product promotion

Respondents argue that if the moratorium agreement succeeded in generating early sales of 3T3, such sales would garner publicity for this new product. Hoffman, Tr. 360. The Brown University case rejected that claim that a price restraint may benefit consumers by channeling resources into efforts to improve quality. "This is not the kind of pro-competitive virtue contemplated under the [Sherman] Act, but rather one mere consequence of limiting price competition." 5 F.3d at 675. In the same way, suppressing promotion of 3T1 and 3T2 may by default lead consumers to pay greater attention to 3T3, but this is not a pro-competitive benefit. n45

n45 See also NCAA, 468 U.S. at 116-117 (increased ticket sales is not a legitimate justification for limitations on telecasts of college football); Catalano, 446 U.S. at 649.

The moratorium agreement was not a necessary strategy for publicizing 3T3. Warner had many less restrictive alternative methods of generating attention for 3T3. F. 168. In lieu of raising the price of 3T1 and 3T2, Respondents could have reduced the price of 3T3. F. 169.

F. Respondents' Withdrawal From the Moratorium

In the United States during the moratorium period (August 1 to October 15, 1998), there was no significant discounting or advertising of 3T1 by PolyGram; and during the moratorium period, there was no significant discounting or advertising of 3T2 by Warner. F. 170-76. Respondents assert, however that PolyGram withdrew from the moratorium agreement, that PolyGram did not implement the agreement, and that neither

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PolyGram nor Warner would have discounted or advertised 3T1/3T2 regardless of any agreement.

Withdrawal from an unlawful agreement does not erase the underlying violation. *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 224 n.59 (1940). n46 The government is not required to prove any overt acts in furtherance of the alleged conspiracy. n47 An accepted invitation is not immune from liability under Section 5. n48

n46 See also *United States v. Hayter Oil Co.*, 51 F.3d 1265, 1270-71 (6th Cir. 1995); *United States v. Mobile Materials, Inc.*, 871 F.2d 902, 908 (10th Cir. 1989) (per curiam), modified per curiam, 881 F.2d 866 (10th Cir. 1989); *Konik v. Champlain Valley Physicians Hosp. Med. Ctr.*, 733 F.2d 1007, 1019 (2d Cir. 1984).

n47 *Summit Health, Ltd. v. Pinhas*, 500 U.S. 322, 330 (1991); *Nash v. United States*, 229 U.S. 373, 378 (1913) (Holmes, J.) (Sherman Act "does not make the doing of any act other than the act of conspiring a condition of liability"); *Mobile Materials, Inc.*, 871 F.2d at 908; *United States v. Miller*, 771 F.2d 1219, 1226 (9th Cir. 1985); *United States v. Portsmouth Paving Corp.*, 694 F.2d 312, 324 (4th Cir. 1982).

n48 Even an unaccepted invitation to collude may raise antitrust liability. *United States v. American Airlines*, 743 F.2d 1114, 1121 (5th Cir. 1984).

Paul Saintilan testified at deposition that in July 1998 he informed Warner executive Anthony O'Brien that PolyGram would not implement the moratorium. But O'Brien credibly testified at trial and denied that such conversation ever occurred. No PolyGram representative ever told O'Brien that PolyGram intended to withdraw from its agreement not to compete. O'Brien, Tr. 473.

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The documentary record supports O'Brien. In July 1998, in an effort to conceal his actions, Saintilan destroyed documents regarding the moratorium, but he had no incentive to destroy exculpatory materials. JX 76 at UMG000213. It is most likely then that the conversation described by Saintilan never took place.

Warner and PolyGram attorneys exchanged draft versions of what later became the August 10 letter from O'Brien to Saintilan (purporting to reject the moratorium proposed by PolyGram). F. 160-62. These communications cannot constitute PolyGram's effective withdrawal from the conspiracy. The August 10 letter describes Warner's intended conduct in Europe, not PolyGram's, and the August 10 letter was countermanded by O'Brien. F. 160-63.

Warner perceived and understood that PolyGram was in fact complying with the moratorium on a worldwide basis between August 1 and October 15, 1998. F. 170, 173-74, 177-81. PolyGram's supposed "withdrawal" was not communicated to Warner: only after October 15 did Warner promote 3T2; and only after October 15 did Warner anticipate that PolyGram would discount 3T1. F. 182. Little weight can be accorded to deposition testimony that conflicts with the contemporaneous written record.
n49

n49 *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947); *Millar v. FCC*, 707 F.2d 1530, 1541 (D.C. Cir. 1983); *Gainesville Utils. Dep't v. Florida Power & Light Co.*, 573 F.2d 292, 301 n.14 (5th Cir. 1978); *Pension Benefit Guar. Corp. v. Envirodyne Industries, Inc.*, 1988 U.S. Dist. LEXIS 16044 *2-3 (N.D. Ill. 1988).

CONCLUSIONS OF LAW

I. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding, and over Respondents PolyGram Holding, Inc., Decca Music Group Limited, UMG Recordings, Inc., and Universal Music & Video Distribution Corp. (collectively, "PolyGram" or "Respondents").

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II. At all relevant times, each respondent was a corporation within the meaning of Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

III. Respondents' acts and practices, including the challenged acts and practices, are in or affect commerce as "commerce" is defined in the Federal Trade Commission Act, 15 U.S.C. § 44.

IV. Respondents have entered into contracts, combinations, or conspiracies with their competitor, Warner Music Group ("Warner"), constituting unfair methods of competition, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

V. In 1998, PolyGram and Warner agreed to observe a "moratorium" on competitive activity. The parties agreed to forgo discounting and advertising of older Three Tenors audio and video products (referred to as "3T1" and "3T2") for a period of time following the release of a new Three Tenors recording (referred to as "3T3").

VI. Certain categories of restraints almost always tend to raise price or reduce output, and hence are presumptively anticompetitive.

VII. The moratorium agreement between PolyGram and Warner to forgo discounting and advertising is likely, absent an efficiency justification, to lead to higher prices or reduced output, and hence is presumptively anticompetitive.

VIII. Where a presumptively anticompetitive agreement is proven, the burden shifts to the Respondents to prove the existence of a plausible and valid efficiency justification for the restraint. That is, Respondents must show that the moratorium was necessary in order to promote competition and benefit consumers.

IX. Where a presumptively anticompetitive restraint is ancillary to a collaboration, Respondents must show that the

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restraint is necessary in order to achieve the pro-competitive benefits of that collaboration.

X. An agreement entered into following the formation of a joint venture to forgo discounting and advertising for the pre-existing, separately produced, and separately distributed products of the individual venturers is not ancillary to the joint venture agreement. The price restraint is per se illegal.

XI. Where the proffered efficiency justifications are either implausible on their face or invalid in view of the relevant facts, the presumptively anticompetitive restraint can be condemned, without assessing market power or examining actual anticompetitive effects.

XII. An efficiency argument is implausible (insufficient on its face) where, for example, it is pretextual, inapposite to the factual circumstances presented, or where the argument is premised upon the claim that competition is unworkable or undesirable.

XIII. An efficiency justification should be rejected as invalid where, for example, it is speculative or unproven, where the argument sweeps too broadly, where there is a less restrictive alternative, or where the restraint is not an effective remedy for the competitive problem that it purports to address.

XIV. Respondents have not met their burden of identifying a plausible efficiency justification for the challenged restraints. Respondents' claim that the moratorium agreement addresses a market failure in Europe can not justify the agreement to restrain competition in the United States.

XV. Even if the justifications proffered by Respondents were deemed plausible, Respondents have not met their burden of proving the existence of a valid efficiency justification.

XVI. In order to demonstrate a valid free-riding defense, Respondents must show that: (i) absent the challenged restraints, free-riding was likely to have the effect of eliminating some

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valued service from the marketplace; (ii) there was no reasonable means by which the competitor that benefitted from the valued service (the alleged free rider) could have compensated the firm that was providing such service; and (iii) there were no less restrictive alternatives. Respondents have satisfied none of these requirements.

XVII. In the recorded music industry, it is common for advertising and other promotional activity to benefit a competitor different from (and in addition to) the firm that funded the advertising. Generally, this does not lead record companies to abandon or even significantly to curtail advertising. The evidence does not support a finding that the venturers' advertising expenditures in support of 3T3 would have significantly decreased in the United States without the moratorium agreement.

XVIII. Where firms that share the benefits from advertising also share the costs of such advertising, free-rider problems are reduced or eliminated. Even assuming that there was a potential free-riding problem in connection with advertising for 3T3, PolyGram and Warner effectively remedied the free-riding problem by sharing the costs of advertising 3T3.

XIX. Other substantially less restrictive alternatives for addressing the purported free-riding concern were also available to PolyGram and Warner. For example, Respondents could have limited the moratorium to Europe (the site of the alleged free-riding problem).

XX. The Three Tenors moratorium agreement was not necessary to eliminate consumer confusion. The evidence does not support a finding that consumers were actually confused in selecting among the various Three Tenors products. Further, the potential for confusion could have been remedied by making the packaging for 3T3 more distinct, and/or by working with retailers to ensure that the Three Tenors products were displayed in a manner that consumers would not find confusing.

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XXI. The claim that suppressing promotion of similar, competing products is necessary in order to eliminate confusion conflicts with the basic policy of the antitrust laws.

XXII. The Three Tenors moratorium agreement was not necessary for the formation of the 3T3 collaboration between Warner and PolyGram.

XXIII. The Three Tenors moratorium agreement was not necessary for the effective marketing of 3T3 in the United States.

XXIV. Modest cost savings may be achieved by any joint selling arrangement; this however is not a sufficient justification for the adoption of presumptively anticompetitive restraints.

XXV. When a firm withdraws from the market at the behest of a rival, this will enable the surviving competitor to generate additional consumer attention, publicity, and sales. These effects may be the by-product of any market division agreement, and are not a cognizable antitrust defense.

XXVI. Section 5 of the FTC Act proscribes anticompetitive agreements. Respondents' claim that the moratorium agreement was not implemented in the United States is not supported by the evidence, and is not a valid antitrust defense.

XXVII. Respondents' claim that they withdrew from the moratorium agreement is not supported by the evidence, and is not a valid antitrust defense.

XXVIII. The acts or practices of Respondents were and are to the prejudice and injury of the public. The acts or practices constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. These acts may recur in the absence of the Order entered in this proceeding.

XXIX. Entry of the Order is in the public interest, and is necessary to protect the public now and in the future.

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CEASE AND DESIST ORDER

"Once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *United States v. E.I. du Pont De Nemours and Co.*, 366 U.S. 316, 334 (1961). "The Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices" so long as the remedy has a "reasonable relation to the unlawful practices found to exist. *Jacob Siegel v FTC*, 327 U.S. 608, 611-13 (1946). Further, "the Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past. . . . It must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity." *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).

The Commission may issue an order even where the respondent has discontinued the illegal practice, where the possibility of a recurrence of the illegal activity exists. n50 Where, as here, the respondents have refused to acknowledge their past lawlessness, this may be viewed as evidence that the illegal activity may recur. *Wilk*, 895 F.2d at 366.

n50 See *United States v. Oregon State Med. Soc'y.*, 343 U.S. 326, 333 (1952); *Wilk v. American Med. Assoc.*, 895 F.2d 352, 366-68 (7th Cir. 1990); *Official Airline Guides, Inc. v. FTC*, 630 F.2d 920, 928 (2d Cir. 1980); see also, *Marlene's, Inc. v. FTC*, 216 F.2d 556, 560 (7th Cir. 1954).

The marketing challenge that gave rise to the Three Tenors moratorium may recur: the fear that a new release by a given artist may lose sales to the artist's older albums. Respondents have recording contracts with several artists that formerly released albums with one of Respondents' competitors. F. 331-32. n51 Universal is engaged in other joint ventures where a similar incentive and opportunity to restrain competition is presented. Universal and Sony have formed a joint venture known as "Pressplay" to distribute music over the Internet. Universal, Sony,

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and other music companies will provide their music to the venture on a non-exclusive basis. This means that music products marketed by the venture may also be marketed (e.g., by Sony) through traditional retail outlets. Absent an order, Universal and Sony may find it profitable to fix prices on products sold to retail stores in order to enhance the venture's internet sales and profits. F.334.

n51 A music label may release an artist from his exclusive recording contract in return for a royalty on the artist's first album on his new label. When this occurs, the two competing labels may have a shared financial interest in the success of a particular album. Hoffman, Tr. 357.

ORDER

I.

1: "PolyGram Holding" means PolyGram Holding, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by PolyGram Holding, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

2: "Decca Music" means Decca Music Group Limited, its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Decca Music Group Limited; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

3: "UMG" means UMG Recordings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by UMG Recordings, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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4: "UMVD" means Universal Music & Video Distribution Corp., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Universal Music & Video Distribution Corp.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

5: "Respondents" means PolyGram Holding, Decca Music, UMG, and UMVD, individually and collectively.

6: "Commission" means the Federal Trade Commission.

7: "Audio Product" means any prerecorded music in any physical, electronic, or other form or format, now or hereafter known, including, but not limited to, any compact disc, magnetic recording tape, audio DVD, audio cassette, album, audiotape, digital audio tape, phonograph record, electronic recording, or digital audio file (i.e., digital files delivered to the consumer electronically to be stored on the consumer's hard drive or other storage device).

8: "Video Product" means any prerecorded visual or audiovisual product in any physical, electronic, or other form or format, now or hereafter known, including, but not limited to, any videocassette, videotape, videogram, videodisc, compact disc, electronic recording, or digital video file (i.e., digital files delivered to the consumer electronically to be stored on the consumer's hard drive or other storage device).

9: "Seller" means any Person other than a Respondent that produces or sells at wholesale any Audio Product or Video Product.

10: "Joint Venture Agreement" means a written agreement between a Respondent and a Seller that provides that the parties to the agreement shall collaborate in the production or distribution (including, without limitation, through the licensing of intellectual property) of Audio Products or Video Products.

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11: An Audio Product or Video Product is "Jointly Produced" by a Respondent and a Seller when, pursuant to a written agreement between such Respondent and such Seller, each contributes significant assets to the production or distribution of the Audio Product or Video Product (including, without limitation, personal artistic services, intellectual property, technology, manufacturing facilities, or distribution networks) to achieve procompetitive benefits. For example and without limitation, an Audio Product or Video Product is "Jointly Produced" by a Respondent and a Seller when (1) such product is manufactured or packaged by such Seller and sold at wholesale by such Respondent, or (2) such product is manufactured or packaged by such Respondent and sold at wholesale by such Seller.

12: "Person" means both natural persons and artificial persons, including, but not limited to, corporations, partnerships, and unincorporated entities.

13: "Officer, Director, or Employee" means any officer or director or management employee of any Respondent with responsibility for the pricing, marketing, or sale in the United States of Audio Products or Video Products.

14: "United States" means the fifty states, the District of Columbia, the Commonwealth of Puerto Rico, and all territories, dependencies, and possessions of the United States of America.

II.

IT IS ORDERED that Respondents shall cease and desist from, directly, indirectly, or through any corporate or other device, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, soliciting, participating in, entering into, attempting to enter into, implementing, attempting to implement, continuing, attempting to continue, or otherwise facilitating or attempting to facilitate any combination, conspiracy, or agreement, either express or implied, with any Seller:

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A. to fix, raise, or stabilize prices or price levels, in connection with the sale in or into the United States of any Audio Product or any Video Product; or

B. that prohibits, restricts, regulates, or otherwise places any limitation on any truthful, non-deceptive advertising or promotion in the United States for any Audio Product or any Video Product.

III.

IT IS FURTHER ORDERED that:

A. It shall not, of itself, constitute a violation of Paragraph II.A. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement to set the prices or price levels for any Audio Product or Video Product when such written agreement is reasonably related to a lawful Joint Venture Agreement and reasonably necessary to achieve its procompetitive benefits.

B. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement that regulates or restricts the advertising or promotion for any Audio Product or Video Product where such written agreement is reasonably related to a lawful Joint Venture Agreement and reasonably necessary to achieve its procompetitive benefits.

C. It shall not, of itself, constitute a violation of Paragraph II.A. of this Order for a Respondent and a Seller to enter into, attempt to enter into, or comply with a written agreement to set the prices or price levels for any Audio Product or Video Product that is Jointly Produced by such Respondent and such Seller.

D. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent and a Seller to enter into, attempt to enter into, or comply with a written agreement that regulates or restricts the advertising or promotion for any Audio Product or

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Video Product that is Jointly Produced by such Respondent and such Seller.

E. It shall not, of itself, constitute a violation of Paragraph II.B. of this Order for a Respondent to enter into, attempt to enter into, or comply with a written agreement, industry code, or industry ethical standard that is: (1) intended to prevent or discourage the advertising, marketing, promotion, or sale to children of Audio Products or Video Products labeled or rated with a parental advisory or cautionary statement as to content, and (2) reasonably tailored to such objective.

F. In any action by the Commission alleging violations of this Order, each Respondent shall bear the burden of proof in demonstrating that its conduct satisfies the conditions of Paragraph(s) III.A., III.B., III.C, and III.D. of this Order.

IV.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent has complied and is complying with this Order.

B. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, each Respondent shall file with the Commission a verified written report:

1. setting forth in detail the manner and form in which it has complied and is complying with this Order; and

2. identifying the title, date, parties, term, and subject matter of each agreement between any Respondent and any Seller, entered into or amended on or after the date this Order becomes final, that: (a) fixes, raises, or stabilizes prices or price levels in

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connection with the sale in or into the United States of any Audio Product or Video Product, or (b) prohibits, restricts, regulates, or otherwise places any limitation on any truthful, non-deceptive advertising or promotion in the United States for any Audio Product or any Video Product (other than those Audio Products and Video Products that are Jointly Produced).

PROVIDED HOWEVER that Respondents shall not be required to identify in their reports to the Commission any agreement that: (i) was previously identified to the Commission pursuant to Paragraph IV.B.2., and (ii) was not amended following such previous identification.

C. Each Respondent shall retain copies of all written agreements identified pursuant to Paragraph IV.B.2. above; and shall file with the Commission, within ten (10) days' notice to the Respondent, any such written agreements as the Commission may require.

V.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, upon written request, each Respondent shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and

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documents in the possession or under the control of the Respondent relating to any matters contained in this Order; and

B. Upon five (5) days' notice to the Respondent and without restraint or interference from it, to interview officers, directors, or employees of the Respondent.

VII.

IT IS FURTHER ORDERED that each Respondent shall:

A. Within thirty (30) days after the date on which this Order becomes final, send a copy of this Order by first class mail to each of its Officers, Directors, and Employees;

B. Mail a copy of this Order by first class mail to each person who becomes an Officer, Director, or Employee, no later than (30) days after the commencement of such person's employment or affiliation with the Respondent; and

C. Require each Officer, Director, or Employee to sign and submit to the Respondent within thirty (30) days of the receipt thereof a statement that: (1) acknowledges receipt of the Order; (2) represents that the undersigned has read and understands the Order; and (3) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject the Respondent to penalties for violation of the Order.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate twenty (20) years after the date on which the Order becomes final.

Complaint

IN THE MATTER OF

GUESS?, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4091; File No. 0223260
Complaint, July 30, 2003--Decision, July 30, 2003*

This consent order, among other things, prohibits Respondents Guess?, Inc. and Guess.com, inc. (“Guess”) – together an international company that designs and produces men’s, women’s, and children’s clothing and accessory products that are marketed, distributed, and sold under various Guess brand names through its own stores, a limited number of independent retailers, and its online store – in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service, from misrepresenting the extent to which it maintains and protects the security, confidentiality, or integrity of any personal information collected from or about consumers. The order also requires Guess to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. In addition, the order requires Guess to obtain – within one year, and on a biannual basis thereafter for twenty years – an assessment and report from a qualified, objective, independent third-party professional, certifying that (1) Guess has in place a security program that provides protections that meet or exceed the protections required by Part II of this order; and (2) Guess’s security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumer’s personal information has been protected.

Participants

For the Commission: *Jeffrey S. Davidson, Alain Sheer, Jessica L. Rich, Joel Winston, Louis Silversin, Gerard R. Butters, and Paul A. Pautler.*

For the Respondents: *Debra Valentine, O’Melveny & Myers, and Deborah Siegel, Guess.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Guess?, Inc., a corporation, and Guess.com, inc., a corporation, (“Respondents”) have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Guess?, Inc. is a Delaware corporation with its principal office or place of business at 1444 S. Alameda Street, Los Angeles, California 90021. Respondent Guess.com, inc. is a Delaware corporation and a wholly-owned subsidiary of Respondent Guess?, Inc. Its principal office or place of business is at 1444 S. Alameda Street, Los Angeles, California 90021.
2. Respondent Guess?, Inc. designs and produces, or licenses others to produce, men’s, women’s, and children’s clothing and accessory products. These products are marketed, distributed and sold under various Guess? brand names through its own stores, independent retailers, and www.guess.com, a website owned and operated by Respondent Guess.com, inc.
3. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.
4. Respondents have marketed and sold Guess-branded clothing and accessory products to consumers online at www.guess.com since June 1998. In order to make purchases from the website, consumers must pay using a credit or debit card. To complete these transactions, consumers must provide personal information, including, but not limited to, name, address, and credit or debit card number and expiration date. Respondents store this information in particular locations (called “tables”) within

Complaint

databases that support or connect to the website. For example, the credit card numbers received from purchasers on the website are stored in a single database table. Respondents also store product information, such as the sizes and colors in which a shirt is available, in other tables contained within the same databases.

5. Like most e-commerce websites, visitors interact with Respondents' website using a software program called an "application." Respondents' application was designed so that a visitor could use it to obtain product information from certain database tables, as well as to supply transaction information that was then stored in other tables in the databases. To facilitate communications between the website and a visitor, the application was designed to automatically present in clear readable text any information retrieved from or supplied to the databases.
6. Since June 1998, Respondents have disseminated or caused to be disseminated privacy policies on www.guess.com, including but not necessarily limited to that attached as Exhibit A, containing the following statements:

Privacy Policy

At GUESS.com, we are committed to protecting your privacy. We firmly believe that electronic security and privacy are necessary for the continued success of the Internet. In support of this, we only use the personal information that you provide to create a more personalized and entertaining experience for you, in accordance with the terms outlined below.

* * *

Security

This site has security measures in place to protect the loss, misuse and alteration of the information under our control.

Complaint

All orders are transmitted over secure Internet connections using SSL (Secure Sockets Layer) encryption technology. All of your personal information including your credit card information and sign-in password are stored in an unreadable, encrypted format at all times. This Website and more importantly all user information, is further protected by a multi-layer firewall based security system.

Exhibit A: GUESS.com Privacy Policy,
<http://www.guess.com/section.asp?section=privacy> (emphasis in original).

7. Respondents have disseminated or caused to be disseminated Frequently Asked Questions on www.guess.com, including but not necessarily limited to that attached as Exhibit B, containing the following statements:

Q: What is the Information Security Policy for GUESS? Online?

A: Providing a safe and secure environment for your order information is our top priority. Taking advantage of Secure Sockets Layer (SSL) technology, GUESS? ensures the security of your online transaction. The GUESS? Online Store is powered by Microsoft and Verisign and uses Cybersource SSL technology - the industry standard for encryption technology to create a secure transaction environment for commerce on the Internet. SSL technology encrypts files allowing only GUESS? to decode your information.

Exhibit B: About Guess?,
<http://www.guess.com/section.asp?section=help> (emphasis in original).

8. Since at least October 2000, Respondents' application and website have been vulnerable to commonly known or reasonably foreseeable attacks from third parties attempting

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to obtain access to customer information stored in Respondents' databases. These attacks include, but are not limited to, web-based application attacks such as "Structured Query Language" ("SQL") injection attacks. Such attacks occur when an attacker enters certain characters in the address (or URL) bar of a standard web browser to direct the application to obtain information from the databases that support or connect to the website. Through such an attack, the application could be manipulated to gain access, in clear text, to every table in the www.guess.com databases, including the tables containing the credit card information supplied by purchasers.

9. Respondents created these vulnerabilities by failing to implement reasonable and appropriate measures to secure and protect the databases that support or connect to the website. Among other things, Respondents failed to: adopt policies and procedures adequate to protect sensitive consumer information collected through the website; test or otherwise assess the website's or the application's vulnerability to attacks; and implement reasonable measures to prevent website visitors from gaining access to database tables containing sensitive personal information about other consumers.
10. The risk of web-based application attacks is commonly known in the information technology industry, as are simple, publicly available measures to prevent such attacks. Security experts have been warning the industry about these vulnerabilities since at least 1997; in 1998, at least one security organization developed, and made available to the public at no charge, security measures which could prevent such attacks; and in 2000, the industry began receiving reports of successful attacks on web-based applications.

Complaint

11. In February, 2002, a visitor to the website, using an SQL injection attack, was able to read in clear text credit card numbers stored in Respondents' databases.
12. Through the means described in Paragraphs 6 and 7, Respondents have represented, expressly or by implication, that the personal information they obtained from consumers through www.guess.com was stored in an unreadable, encrypted format at all times.
13. In truth and in fact, the personal information Respondents obtained from consumers through www.guess.com was not stored in an unreadable, encrypted format at all times. Using a standard web browser, a commonly known attack could be employed to manipulate the web application and gain access, in clear readable text, to sensitive personal information about other consumers, including but not limited to, consumer names and credit card numbers and expiration dates. Therefore, the representation set forth in Paragraph 12 was false or misleading.
14. Through the means described in Paragraphs 6 and 7, Respondents have represented, expressly or by implication, that they implemented reasonable and appropriate measures to protect the personal information they obtained from consumers through www.guess.com against loss, misuse, or alteration.
15. In truth and in fact, Respondents did not implement reasonable and appropriate measures to protect the personal information they obtained from consumers through www.guess.com against loss, misuse, or alteration. In particular, Respondents failed to implement procedures that were reasonable and appropriate to: (1) detect reasonably foreseeable vulnerabilities of their website and application and (2) prevent visitors to the website from exploiting such vulnerabilities and gaining access to sensitive consumer data. Therefore, the

Complaint

representation set forth in Paragraph 14 was false or misleading.

16. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this thirtieth day of July, 2003, has issued this complaint against Respondents.

By the Commission.

EXHIBIT A



WOMEN MEN GIRLS BOYS BABY GIRLS BABY BOYS

MODELS &
MORE

GI

Visions Of GUESS A Second Decade Of GUESS Coffee Table Book



Privacy Policy

At GUESS.com, we are committed to protecting your privacy. We firmly believe that electronic security and privacy are necessary for the continued success of the Internet. In support of this, we only use the personal information that you provide to create a more personalized and entertaining experience for you, in accordance with the terms outlined below.

Kid's policy (individuals under 13 years of age). GUESS.com is committed to protecting the safety of children online. In compliance with the Children's Privacy Protection Act of 1998, GUESS.com will never knowingly request or use personal information from children under 13 years of age without prior parental consent. If GUESS.com receives actual knowledge that a subscriber is under 13 years of age, GUESS.com will eliminate all personal information relating to this subscriber from our files.

Information We Gather

We use all information provided during registration and personalization to provide personalized content and services. Any account information you supply will be used only to process requested commerce transactions or to contact you regarding a specific transaction. GUESS.com may also use this information in order to generate aggregate reports that help us determine how to improve our users' experience. This data is anonymous and does not contain any personally identifiable information. GUESS.com will not disclose your user information to any outside organization without your consent. However, GUESS.com may disclose user information to the government and/or third parties when we have reason to believe that disclosure of such information is necessary to identify or bring legal action against someone who may be violating our Terms and Conditions or otherwise causing harm to GUESS.com or anyone who could be victimized by such activities, and where otherwise required by law or by legal process.

We may also use your contact information to e-mail you newsletters that inform you of new products and special features at GUESS.com. We may also offer you special promotions from our site or our sponsors. If you prefer not to receive such communications, you may contact us at customerservice@guess.com.

GUESS.com also derives user information through some simple technical methods. We may use data-tracking software that lets us know what areas of the site you visit most often. This helps us present you with the information and features in which you are most interested.

We may use your IP (Internet protocol) address to help diagnose problems with our server, and to administer our Web site. Your IP address is used to help identify you and your shopping cart and to gather broad demographic information.

Our site uses cookies to keep track of your shopping cart. We use cookies to deliver content specific to your interests and to save your password so you don't have to re-enter it each time you visit our site.

Security

This site has security measures in place to protect the loss, misuse and alteration of the information under our control. All orders are transmitted over secure Internet connections using SSL (Secure Sockets Layer) encryption technology. All of your personal information including your credit card information and sign-in password are stored in an unreadable, encrypted format at all times. This Website and more importantly all user information, is further protected by a multi-layer firewall based security system.

Contact Us

If you have any questions about this privacy statement, the practices of this site, or your dealings with GUESS.com, you can contact us:

Customer Service
GUESS.com
1444 Alameda St.
Los Angeles, CA 90021
customerservice@guess.com

[GIFT CARDS](#) [SIGN IN](#) [YOUR SHOPPING BAG](#) [CHECKOUT](#) [SITE MAP](#) [SIZE CHART](#) [STORE LOCA](#)

We can accept orders within the 48 continental United States, Alaska, and Hawaii.
We cannot accept orders in Canada at this time.

EXHIBIT B



WOMEN MEN GIRLS BOYS BABY GIRLS BABY BOYS

MODELS &
MORE

GI

Visions Of GUESS A Second Decade Of GUESS Coffee Table Book

Get

[About GUESS?](#)

[Billing](#)

[Care Instructions](#)

[Customer Service](#)

[Gifts](#)

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[Your Profile](#)

About GUESS?

Q: How do I contact GUESS?

A: Depending on the nature of your question, you may reach GUESS one of the following ways.

For assistance in locating a specific item in a retail store, please call:

GUESS? Retail
1-800-39-GUESS

For help locating an employee or specific department, questions regarding retail stores, and information about advertising or licensing, please call:

GUESS? Corporate
1-800-22-GUESS

For online help, information about online ordering and returns, reporting website errors, or receiving assistance in placing a GUESS.com order, please call:

GUESS? Online
Monday through Friday from 8:30 a.m. to 6:00 p.m. (EST)
1-877-44-GUESS

To EMAIL questions related to GUESS? Online, please click [here](#). Emails typically receive a response within 24 hours.

Q: Where is the GUESS? corporate office located?

A: GUESS? corporate headquarters are located in Los Angeles, California. GUESS? also has showroom locations in New York City, Dallas and Atlanta. If you would like to send correspondence to our corporate office, please address it to:

GUESS?, Inc.

1444 South Alameda Street
Los Angeles, CA 90021
U.S.A.

Q: I am doing a report for school, where can I find information about GUESS?

A: Most of the information you need can be found within this website. For information on the history of the company, store locations, financial articles, and recent news items, visit the [GUESS, Inc.](#) section. Information on our models and advertising campaigns can be found within the [Models & More](#) section of the site.

Documents filed with the Securities & Exchange Commission, such as proxy statements, 10-K's, 10-Q's, annual reports, and others, may be found at <http://www.sec.gov>. Choose "Search For Company Filings" under Filings & Forms (EDGAR). Select "Search The EDGAR Archives" under General Purpose Searches. Then, enter the search keyword: "guess."

To obtain a printed copy of an annual report, please submit a written request along with your complete mailing address to:

GUESS?, Inc.

Investors Relations Department
1444 South Alameda Street
Los Angeles, CA 90021
U.S.A.

We are not able to provide detailed answers to specific questions about our advertising or marketing programs, strategic planning, internal systems, policies or other confidential topics.

Q: What is the GUESS? Mission Statement?

A: MISSION STATEMENT:

At GUESS?, we are committed to being a worldwide leader in the fashion industry. We will deliver products and services of uncompromising quality and integrity consistent with our brand and our image.

We are committed to listening and responding to the needs of our customers, associates and business partners and honor their individual value.

We are dedicated to personal and professional enrichment through an environment of open communication, creativity, teamwork, trust and respect. We continue to give back to the community, support humanity and protect the environment as part of our responsibility.

We remain committed to an entrepreneurial spirit that fuels the growth of our Company and achieves increased shareholder value.

Through principled leadership we will embrace diversity, cultivate strength, pride and passion to align our personal life and our professional life.

Q: Where does GUESS? purchase its fabrics?

A: The fabrics used by GUESS? come from vendors in California or are imported from Sri Lanka, Bahrain, India, Korea, Taipan, India, Mexico, Hong Kong, Taiwan, Peru or Brazil.

Q: How did GUESS? get its name?

A: One morning, as the Marciano brothers were driving to work, Georges Marciano saw a McDonald's billboard that read "GUESS WHAT'S IN THE NEW BIG MAC?" The biggest word in the entire phrase was "GUESS." It caught Georges' eye and the name of the company was born. Maurice Marciano added the triangle, and a family friend designed a question mark to complete the logo.

Billing**Q: How can I pay for purchases made at GUESS? Online?**

A: GUESS? Online accepts the following major credit cards:

VISA

MASTERCARD

AMERICAN EXPRESS

DISCOVER

GUESS? GIFT CARD

Q: When is my credit card billed?

A: Your credit card will only be billed when your order is shipped.

Q: Why do I have to pay sales tax on my order?

A: GUESS? is required by law to charge sales tax to orders shipped to California and Kentucky. Sales tax does not apply to orders shipped to addresses in other states.

Care Instructions**Q: How should I care for my GUESS? products?**

A: To fully enjoy your new GUESS? products, make sure you read the item's label and follow the care instructions. Here are a few more tips for keeping your items looking their very best:

For Dark Denim (Raw & Rinse): Add 1/2 cup of white vinegar to the water when you wash your jeans the very first time. This helps to set the dark dye in the fabric. Always wash denim inside out, zipper up, to prevent excess wear and tear and delay fading.

For Ribbed Knits: To maintain an item's shape, wash it in cold water and dry flat. To maximize shrinkage, wash in warm water and dry in hot air.

For Silk Screened Items: Wash items inside out, and lay flat to dry or dry using cool air. Use fabric softener to keep the items soft.

For Items With Rhinestones Or Glitter: Follow the instructions for Silk Screened items.

Customer Service

Q: How can I reach Customer Service?

A: Please email any questions or concerns to a Customer Service Representative by [clicking here](#). You may also call GUESS? Online Customer Service toll-free at 1-877-44-GUESS (or 48377) Monday through Friday from 8:30 a.m. to 6:00 p.m. (EST). If you have questions regarding retail stores, licensing, advertising, or need assistance in locating an employee or department, please call 1-800-22-GUESS.

Gifts**Q: How do I place a gift order?**

A: When placing your order, please select "**Send This As A Gift**" on the Checkout page. Any price tags will be removed and a gift receipt will be included within the order box. You may also include a brief message that will be printed on the gift receipt.

The GUESS? Foundation**Q: How does The GUESS? Foundation select an organization to support? Is my organization eligible?**

A: For an organization to be considered by The GUESS? Foundation, a written request must be submitted detailing the organization's functions with documentation supporting a tax-exempt status. Please direct all inquiries to:

The GUESS? Foundation

1444 South Alameda Street
Los Angeles, California
90021
U.S.A.

Investor's Info**Q: Where can I learn more about GUESS? stock?**

A: To find the latest stock quotes, learn about analyst coverage, or read past and present press releases, please visit the [Investor's Page](#) located in the GUESS?, Inc. section of the site.

Jobs**Q: I am interested in working for GUESS?. Where can I send my resume?**

A: Please send your scanner friendly resume and cover letter to:

GUESS?, Inc.

Department of Human Resources
1444 South Alameda Street
Los Angeles, CA 90021
U.S.A.

For more information, please visit the [GUESS? Work](#) section of the site. If you are within the United States and would like access to an automated listing of specific

employment opportunities, please call 1-800-22-GUESS and enter extension 5988.

Licensing

Q: Can I open a GUESS? store? Can I sell GUESS? products in my store?

A: Please submit a written inquiry, along with your company's profile to:

GUESS?, Inc.

Licensing Department
1444 South Alameda Street
Los Angeles, CA 90021
USA

Modeling Opportunities

Q: How can I become a GUESS? model?

A: GUESS? selects models from around the world who represent the image of a particular campaign. We typically select models already signed with professional agencies. If you are interested in modeling for GUESS?, we suggest you contact a professional modeling agency in your area and have them forward your portfolio to:

GUESS?, Inc.

Advertising Department
1444 South Alameda Street
Los Angeles, CA 90021
U.S.A.

Order Info

Q: How will I know if my order is confirmed?

A: If you provided a valid email address during the Checkout process, you will receive two emails after your order is placed. The first will confirm the details of your order. The second email will arrive when your order has shipped and include your order tracking number.

Q: Where does GUESS? Online accept orders from?

A: We are able to accept orders within the 48 continental United States as well as Alaska and Hawaii.

Out-Of-Stock Items

Q: What happens if I place an order and GUESS? does not have the item in stock?

A: While we make every effort to maintain an ample supply of our stock, occasionally we run out of certain items. Out-of-stock items will be removed from your original order total and a revised total will appear in your shipping confirmation email. Unfortunately, we are unable to accept back orders at this time.

Phone Orders

Q: Can I place my order by phone instead of online?

A: If you would prefer to place your order by phone, please call Customer Service toll-free at 1-877-44-GUESS (or 48377), Monday through Friday, 8:30 a.m. to 6:00 p.m. (EST).

Postcards

Q: I can't view my GUESS? postcard! Help!

A: The directions for opening your postcard are contained in the email you received with your postcard. Simply click on the URL address in the body of the email or cut and paste the URL into your browser window.

Privacy & Security

Q: What is the Customer Information Policy for GUESS? Online?

A: GUESS? compiles customer information in an effort to improve and enhance our customers' online shopping experience. We may use this information for marketing and promotional purposes. At this time, we do NOT provide or sell online customer information to any outside companies or third parties.

If at any time you wish to remove Your Profile information, please email us at customerservice@guess.com and type "Remove Profile Information" in the Subject line of your email.

Q: What is the Information Security Policy for GUESS? Online?

A: Providing a safe and secure environment for your order information is our top priority. Taking advantage of Secure Sockets Layer (SSL) technology, GUESS? ensures the security of your online transaction. The GUESS? Online Store is powered by Microsoft and Verisign and uses Cybersource SSL technology - the industry standard for encryption technology to create a secure transaction environment for commerce on the Internet. SSL technology encrypts files allowing only GUESS? to decode your information.

Retail Stores

Q: Where can I find the closest GUESS? retail store?

A: : If you are within the United States, please shop in the GUESS? Online Store. For worldwide GUESS? retail locations, please use the [Store Locator](#) or call 1-800-39-GUESS (within the United States only).

Q: I saw an item in a GUESS? retail store a while ago, how can I find it?

A: If you need help locating a retail store item, please call 1-800-39-GUESS.

Returns & Exchanges

Q: How can I return or exchange merchandise ordered from GUESS? Online?

A: At GUESS? Online, we want you to be 100% satisfied with your purchases. We'll happily accept the return or exchange of unworn, unwashed or defective items. Need a different size? Color? Style? We'll send it to you! Simply choose one of the following convenient options to make a return or exchange:

Return To A Store

Please bring the item(s) along with your original receipt, photo ID, and the credit card you used when you placed your order, to the closest GUESS? retail store. Please use our [Store Locator](#) to find the closest GUESS? store.

Express Exchange

Need it in a hurry? Simply call toll-free 1-877-44-GUESS and order your replacement merchandise. In-stock merchandise will be shipped within approximately 24 hours at no charge for shipping and handling. We will charge your credit card for new merchandise and refund your credit card for returned merchandise as soon as we receive it.

Return Or Exchange By Mail

Complete the **Return/Exchange Form** included in your original shipment and enclose it with the item in its original packaging (when possible). Affix the enclosed shipping label to ensure correct delivery. When exchanging items, be sure to indicate the replacement item, including the style number, color, and size. Packages must be shipped pre-paid. We cannot accept C.O.D. deliveries.

If you have misplaced your GUESS? Return/Exchange label, please send your pre-paid, insured package to:

GUESS.com

E-Commerce Returns
10610 Freeport Drive
Louisville, KY 40258

Refunds and exchanges are processed when item(s) are received. GUESS? will pay the shipping charges for orders processed as exchanges. Refunds are given for the price indicated on the original receipt. Credits for returned or exchanged merchandise will be issued to the original credit card only. Please allow 1 to 2 billing cycles for the credit to appear on your statement.

Returns Without An Original Receipt

If you no longer have a copy of your original receipt, a refund will be issued for the item's current or most recent sale price. If you have further questions or require additional assistance, please email our Online Customer Service Department by [clicking here](#).

Gift Returns

If you would like to return an item you received as a gift, please follow the for returns or exchanges. Gift returns will be refunded via check to the gift recipient.

Q: What is your return policy?

A: GUESS? will gladly accept returns and exchanges with the original receipt and tags attached for up to 60 days after the original purchase. Sale merchandise may be exchanged only. Returns will be refunded in the method of original payment. Gift recipients may receive a refund check or exchange for equal or lesser value.

Shipping

Q: What are my shipping options and rates?

A: GUESS? Online orders may be shipped one of the following ways:

UPS Next Day Air ®

UPS 2nd Day Air ®

UPS Ground

Q: How long does it take before my order is shipped?

A: Orders placed during regular business hours (Monday through Friday, 8:00 a.m. to 4:00 p.m. EST) are typically shipped within 24 hours.

Q: Can I have my order shipped to multiple addresses?

A: If you would like to send a shipment to more than one address, you will have to place separate online orders for each destination, or place your order by phone at 1-877-44-GUESS (or 48377).

Q: Once my order is shipped, how can I track it?

A: Your shipment confirmation email will contain your GUESS? order tracking number. If you are registered with GUESS? Online, sign in using your Username and Password and go directly to the Order History section. Inside, you'll find a link directly to the UPS site where you will be prompted to enter your order tracking number. Please note: it may take up to 24 hours before your tracking information appears online.

Size Charts

Q: How do I know what size to order?

A: Please visit the [Size Chart](#) section which contains information on sizing and the proper way to take your measurements.

If you have further size or fit questions, please email our Customer Service Department by [clicking here](#). Or call us toll-free at 1-877-44-GUESS (or 48377) Monday through Friday from 8:30 a.m. to 6:00 p.m. (EST).

Technical Questions

Q: What browser works best with the GUESS.com site?

A: Our technical team makes every effort to ensure the site will be compatible with every browser, but the GUESS.com site is optimized for Netscape and Internet Explorer 4.0 browsers and above, with a screen resolution set to 800X600. Javascript and Cookies must be enabled. Please see your browser's help section for more information.

Watches

Q: Who do I contact with service questions about my GUESS? watch?

A: Please contact the GUESS? watch manufacturer, Callanen International, directly by emailing them at WatchInfo@callanen.com. You may also reach them by calling 1-

800-248-3775 or sending a written inquiry to:

Callanen International

165 Water Street
Norwalk, CT 06854
U.S.A.

Your Profile**Q: Why should I save a profile?**

A: By saving Your Profile with a Username and Password, you'll cut your Checkout time in half. Sign in when you make a purchase and we'll automatically fill in the forms with all of your billing and shipping information. You'll also be the first to hear about sales, new merchandise and contests.

[GIFT CARDS](#) [SIGN IN](#) [YOUR SHOPPING BAG](#) [CHECKOUT](#) [SITE MAP](#) [SIZE CHART](#) [STORE LOCA](#)

We can accept orders within the 48 continental United States, Alaska, and Hawaii.
We cannot accept orders in Canada at this time.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 et seq; and

The Respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules.

The Commission having thereafter considered the matter and having determined that it has reason to believe that the Respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure described in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Guess?, Inc. is a Delaware corporation with its principal office or place of business at 1444 S. Alameda Street, Los Angeles, California 90021. Respondent Guess.com, inc. is a Delaware corporation and a wholly-owned subsidiary of

Decision and Order

Respondent Guess?, Inc. Its principal office or place of business is at 1444 S. Alameda Street, Los Angeles, California 90021.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Personal information” shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual’s email address; (d) a telephone number; (e) a social security number; (f) credit and/or debit card information, including credit and/or debit card number and expiration date; (g) a persistent identifier, such as a customer number held in a “cookie” or processor serial number, that is combined with other available data that identifies an individual consumer; or (h) any other information from or about an individual consumer that is combined with (a) through (g) above.

2. Unless otherwise specified, “Respondents” shall mean Guess?, Inc. and its successors and assigns, officers, agents, representatives, and employees, Guess.com, inc. and its successors and assigns, officers, agents, representatives, and employees, and both of them and their successors and assigns, officers, agents, representatives, and employees.

3. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Decision and Order

I.

IT IS ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service, in or affecting commerce, shall not misrepresent in any manner, expressly or by implication, the extent to which Respondents maintain and protect the security, confidentiality, or integrity of any personal information collected from or about consumers.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service, in or affecting commerce, shall establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. Such program shall contain administrative, technical, and physical safeguards appropriate to Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. the designation of an employee or employees to coordinate and be accountable for the information security program.
- B. the identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include

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consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures.

- C. the design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures.
- D. the evaluation and adjustment of Respondents' information security program in light of the results of the testing and monitoring required by subparagraph C, any material changes to Respondents' operations or business arrangements, or any other circumstances that Respondents know or have reason to know may have a material impact on the effectiveness of their information security program.

III.

IT IS FURTHER ORDERED that Respondents obtain an assessment and report from a qualified, objective, independent third-party professional, using procedures and standards generally accepted in the profession, within one (1) year after service of the order, and biannually thereafter, that:

- A. sets forth the specific administrative, technical, and physical safeguards that Respondents have implemented and maintained during the reporting period;
- B. explains how such safeguards are appropriate to Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about consumers;

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- C. explains how the safeguards that have been implemented meet or exceed the protections required by Paragraph II of this order; and
- D. certifies that Respondents' security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of personal information is protected and, for biannual reports, has so operated throughout the reporting period.

Each assessment and report required by this Paragraph shall be prepared by a person qualified as a Certified Information System Security Professional (CISSP) or holding Global Information Assurance Certification from the SysAdmin, Audit, Network, Security Institute; or by a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission. Respondents shall provide the first assessment and report to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after it is prepared. All subsequent biannual reports shall be retained in accordance with Paragraph IV. B. of this order and provided to the Associate Director of Enforcement upon request.

IV.

IT IS FURTHER ORDERED that Respondents shall maintain, and upon request make available to the Federal Trade Commission for inspection and copying, a print or electronic copy of each document relating to compliance, including but not limited to:

- A. for a period of five (5) years:
 - 1. a sample copy of each different print, broadcast, cable, or Internet advertisement, promotion, information collection form, Web page, screen, email message, or other

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document containing any representation regarding Respondents' online collection, use, and security of personal information from or about consumers. Each Web page copy shall be dated and contain the full URL of the Web page where the material was posted online. Electronic copies shall include all text and graphics files, audio scripts, and other computer files used in presenting the information on the Web. *Provided, however*, that after creation of any Web page or screen in compliance with this order, Respondents shall not be required to retain a print or electronic copy of any amended Web page or screen to the extent that the amendment does not affect Respondents' compliance obligations under this order, and

2. any documents, whether prepared by or on behalf of Respondents, that contradict, qualify, or call into question Respondents' compliance with this order; and
- B. for a period of three (3) years after the date of preparation of each previous assessment and report required under Paragraph III of this order, and for the initial assessment and report, from the date the order is entered until two years following preparation of the assessment and report: all reports, studies, reviews, audits, audit trails, security assessments, risk assessments, policies, training materials, logs (from devices that detect or prevent attacks such as firewalls and intrusion detection systems), and plans (including the assessments and reports required under Paragraph III), whether prepared by or on behalf of Respondents, relating to Respondents' compliance with Paragraphs II and III of this order.

V.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees,

Decision and Order

agents, and representatives having managerial responsibilities relating to the subject matter of this order. Respondents shall deliver this order to such current personnel within thirty (30) days after service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change in either corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in either corporate name or address. *Provided, however,* that, with respect to any proposed change in either corporation about which either Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents shall, within one hundred and twenty (120) days after service of this order, and at such other times as the Commission may require, file with the Commission an initial report, in writing, setting forth in detail the manner and form in which they have complied with this order.

Decision and Order

VIII.

This order will terminate on July 30, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. any Paragraph in this order that terminates in less than twenty (20) years;
- B. this order's application to any Respondent that is not named as a defendant in such complaint; and
- C. this order if such complaint is filed after the order has terminated pursuant to this Paragraph.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Paragraph as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, a consent agreement from Guess?, Inc. and Guess.com, inc. (“Guess”).

The consent agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Guess is an international company that designs and produces men’s, women’s, and children’s clothing and accessory products. The company’s products are marketed, distributed, and sold under various Guess brand names through its own stores, a limited number of independent retailers, and, its online store at www.guess.com. This matter concerns alleged false or misleading representations Guess made to consumers about the security of personal information collected online through www.guess.com, Guess’ online store.

The Commission’s proposed complaint alleges that Guess misrepresented that the personal information it obtained from consumers through www.guess.com was stored in an unreadable, encrypted format at all times. The complaint alleges that this representation was false because a commonly known attack could and was used to gain access in clear readable text to sensitive personal information, including credit card numbers, that Guess obtained from consumers.

The proposed complaint also alleges that Guess represented that it implemented reasonable and appropriate measures to protect the personal information it obtained from consumers through www.guess.com against loss, misuse, or alteration. The complaint alleges this representation was false because Guess did not employ

Analysis

appropriate measures to detect reasonably foreseeable vulnerabilities and prevent their exploitation.

The proposed order applies to Guess' collection and storage of personal information from or about consumers in connection with its online business. It contains provisions designed to prevent Guess from engaging in practices similar to those alleged in the complaint in the future.

Specifically, Part I of the proposed order prohibits Guess, in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service, from misrepresenting the extent to which it maintains and protects the security, confidentiality, or integrity of any personal information collected from or about consumers.

Part II of the proposed order requires Guess to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to Guess's size and complexity, the nature and scope of its activities, and the sensitivity of the personal information collected from or about consumers. Specifically, the order requires Guess to:

- Designate an employee or employees to coordinate and be accountable for the information security program;
- Identify material internal and external risks to the security, confidentiality, and integrity of customer information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment must include consideration of risks in each area of relevant operation.

Analysis

- Design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures.
- Evaluate and adjust its information security program in light of the results of testing and monitoring, any material changes to its operations or business arrangements, or any other circumstances that Guess knows or has reason to know may have a material impact on its information security program.

Part III of the proposed order requires that Guess obtain within one year, and on a biannual basis thereafter, an assessment and report from a qualified, objective, independent third-party professional, certifying that: (1) Guess has in place a security program that provides protections that meet or exceed the protections required by Part II of this order; and (2) Guess's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumer's personal information has been protected.

Parts IV through VII of the proposed order are reporting and compliance provisions. Part IV requires Guess's to retain documents relating to compliance. For most records, the order requires that the documents be retained for a five-year period. For the assessments and supporting documents, Guess must retain the documents for three years after the date that each assessment is prepared. Part V requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates that Guess submit compliance reports to the FTC. Part VIII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify their terms in any way.

Complaint

IN THE MATTER OF

WASHINGTON UNIVERSITY PHYSICIAN NETWORKCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4093; File No. 0210188
Complaint, August 22, 2003--Decision, August 22, 2003*

This consent order, among other things, prohibits Respondent Washington University Physician Network – a not-for-profit corporation consisting of 900 faculty physicians and 600 community physicians who provide health care services in the greater St. Louis area, and whose sole legal member is Washington University – from entering into or facilitating any agreement between or among any physicians (1) to negotiate with payors on any physician’s behalf; (2) to deal, refuse to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than the respondent. The order also prohibits the respondent from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondent from attempting to engage in, or from encouraging, pressuring, or attempting to induce any person to engage in, any action prohibited by the order. The order also requires the respondent to send notice of the order and complaint to all its participating physicians, employees and principals – and to all payors it has contacted since January 1, 1998, concerning the provision of physician services – and to terminate, without penalty, any preexisting contract with a payor upon receipt of a payor’s written request to terminate the contract.

Participants

For the Commission: *Garry Gibbs, Melea Epps Greenfeld, David R. Pender, Eric D. Rohlck, Daniel P. Ducore, Jeffrey W. Brennan, Louis Silvia, Jr. and Mary T. Coleman.*

For the Respondent: *John J. Miles and E. John Steren, Ober Kaler.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority

Complaint

vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that the Washington University Physician Network (“WUPN”) has violated and is violating Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its Complaint stating its charges in that respect as follows:

Nature of the Case

1. This matter concerns horizontal agreements among competing physicians in the greater St. Louis, Missouri, area, to fix prices charged to health care plans and other third-party payors (“payors”), and to refuse to deal with payors except on collectively agreed-upon terms. The physicians orchestrated these price-fixing agreements and concerted refusals to deal through WUPN, and their conduct increased the prices of physician services in the greater St. Louis area.

Respondent WUPN

2. WUPN is organized under The General Not for Profit Corporation Law of Missouri, and is doing business under and by virtue of the laws of the State of Missouri. WUPN’s office and principal place of business is located at 7425 Forsyth Boulevard, Suite 307, Clayton, Missouri 63105.
3. Washington University and approximately 1,500 physicians are members of WUPN. WUPN, among other things, negotiates on the physicians’ behalf for contracts with payors. All of the WUPN physicians practice medicine in the greater St. Louis area. These physicians include not only approximately 900 members of the clinical faculty of the Washington University School of Medicine (“faculty physicians”), but also approximately 600 independent physicians, whom WUPN refers to as “community physicians.”

Complaint

4. At all times relevant to this Complaint, WUPN's community physicians have been engaged in the business of providing medical services to patients for a fee. WUPN's faculty physician members are full-time, salaried employees of the Washington University School of Medicine. Except to the extent that competition has been restrained as alleged herein, WUPN's community physicians compete with one another and with faculty physician members for the provision of physician services.

The Commission Has Jurisdiction over WUPN

5. WUPN's general business activities and those of its members, including the acts and practices herein alleged, are in or affecting "commerce" as defined in the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 44.
6. WUPN is a corporation within the meaning of Section 4 of the FTC Act. Although WUPN's articles of incorporation and by-laws designate Washington University, a non-profit corporation, as its "sole member" for purposes of Missouri corporation law, WUPN's community physicians are "members" of the corporation within the meaning of Section 4 of the FTC Act. WUPN engages in substantial activities for the pecuniary benefit of its for-profit community physician members.
7. WUPN is governed by its Board of Directors, which includes 29 "Voting Directors," a majority of whom (16) are community physicians. These community physician board members are elected by WUPN's community physician membership. The board's remaining voting members are faculty physicians chosen by Washington University.
8. WUPN regularly and in the ordinary course of business classifies its community physicians as "members," and conducts its business affairs in a manner that demonstrates that the community physicians are "members" of WUPN. To

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participate in WUPN's network and utilize WUPN's contract negotiation and other services, a community physician must complete a WUPN "Membership Application." WUPN's "Membership and Credentialing Committee," a 12-member panel of board members and appointees, evaluates the physician's credentials and recommends to the board the physician's eligibility for membership. Once community physicians become members, they receive a "New Member Information Packet" and are required to pay annual WUPN membership dues.

9. Community physicians, through their elected representatives on the board, actively participate in WUPN's management and business operations. WUPN's activities substantially advance its community physician members' economic interests, including providing discounted insurance rates, group purchasing, continuing medical education, and financial planning opportunities; and engaging in lobbying, marketing, and public relations on behalf of its community physicians.

Overview of Market and Physician Competition

10. WUPN's community physicians provide health care services to patients in St. Louis city and St. Louis County, Missouri; St. Charles and Jefferson Counties in Missouri; and Madison County, Illinois ("the greater St. Louis area").
11. Physicians often deal with payors through contracts that establish the terms and conditions, including prices and other competitively significant terms, pursuant to which the physicians provide medical services to patients who are enrollees in the payors' health insurance plans. Payors may also develop and sell access to networks of physicians to employers and other purchasers of health insurance benefits. Physicians entering into payor contracts often agree to reductions in their compensation to obtain access to additional patients made available by the payors' relationship with enrollees of their health insurance plans.

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Physician-payor contracts may reduce payors' costs, enable them to lower the price of health insurance, and reduce out-of-pocket medical care expenditures by subscribers to the payors' health insurance plans.

12. Absent agreements among them to the contrary, competing physicians decide unilaterally whether to enter into contracts with payors to provide services to enrollees of the payors' health insurance plans, and on the prices and other terms and conditions of dealing that they will accept under such contracts.
13. Medicare's Resource Based Relative Value System ("RBRVS") is a system used by the United States Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. In general, payors make contract offers to individual physicians or groups at a price level specified as some percentage of the RBRVS fee for a particular year (*e.g.*, "110% of 2002 RBRVS").
14. In light of WUPN's large number of member physicians and the extensive geographic territory that they collectively cover in the greater St. Louis area, payors believe that, to be competitively marketable in that area, their health insurance plans must offer physician networks that include WUPN's physician members.

**WUPN Negotiated Payor Contracts
on the Physicians' Behalf**

15. WUPN was established in 1993 to promote, among other things, the collective economic interests of its community physicians by increasing their negotiating leverage with payors. Among other things, WUPN, through its board, develops guidelines for negotiating, reviewing, approving,

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rejecting, terminating, and renewing payor contracts; approves price terms for dealing with payors; establishes procedures for credentialing WUPN's physicians; approves formulas for distributing revenues among the School of Medicine and community physicians from payor contracts; and establishes billing and payment procedures for the community physicians. WUPN has implemented agreements among its physician members to restrain competition by, among other things, engaging in collective negotiations over price and other terms and conditions of dealing with payors, and resisting payors' cost containment measures. In 2000, WUPN reported that it had "successfully negotiated 25 managed care fee-for-service contracts for its members, most of which have very favorable terms when compared to contracts entered into on an individual basis or through another organization."

16. WUPN negotiates payor contracts, including the price terms therein, on the collective behalf of its faculty physicians and community physicians. Representatives of WUPN's management committee, a 12-member panel consisting of physician board members and other board appointees, negotiate directly with payors and report on the progress of their negotiations to the board. This committee advises the board on which proposed payor price terms to accept or reject, and which payor contracts to terminate or continue. The board decides whether to accept or reject a payor contract, including the price terms contained therein, upon the approval of a majority of the community physician directors and of the faculty physician directors present at the board meeting, so long as a majority of the board is present.
17. WUPN's member physicians sign an agreement appointing WUPN as their agent in contract negotiations with payors. If a WUPN member physician participates in a payor's health plan through a contract that WUPN negotiated after the same physician contracted to participate in the same plan through another group contract, then WUPN informs that

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payor that the WUPN contract supersedes the payor's pre-existing contract with that physician.

Negotiations with Blue Cross Blue Shield of Missouri

18. Blue Cross Blue Shield of Missouri ("BCBS") is a payor doing business in the greater St. Louis area. At a November 2000 board meeting, WUPN's management committee reported that its representatives had begun negotiating on behalf of WUPN's member physicians for a new contract with BCBS. WUPN's then-current contract with BCBS was scheduled to expire on March 31, 2001. Pursuant to their agreement with each other and with WUPN, the community physicians and faculty physicians acted in concert concerning whether and on what terms, including price, to deal with BCBS.
19. On February 26, 2001, WUPN demanded in writing that BCBS pay specific, substantial price increases before its member physicians would agree to participate in BCBS's several health plan products. For example, WUPN required that BCBS pay its member physicians 140% of 2001 RBRVS for their participation in BCBS's "BlueChoice" product. On March 19, 2001, BCBS counter proposed much smaller rate increases to WUPN. BCBS's proposed terms included, with respect to the BlueChoice product, payment levels of 85% to 110% of 2001 RBRVS, depending on the covered medical procedure. WUPN rejected this offer and, at an April 2001 board meeting, its management committee asked for and received the board's permission to issue a notice of termination to BCBS.
20. In May of 2001, shortly before the threatened termination, BCBS met WUPN's demands for substantial price increases. BCBS agreed to pay WUPN's physician members 140% of RBRVS for their participation in the BlueChoice plan. BCBS also agreed to meet WUPN's price demands for the other BCBS products.

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Negotiations with CarePartners

21. CarePartners is a payor doing business in the greater St. Louis area. Pursuant to their agreement with each other and with WUPN, the community physicians and faculty physicians acted in concert concerning whether and on what terms, including price, to deal with CarePartners. On February 1, 2000, at a WUPN board meeting, the management committee reported on a meeting that it recently held with CarePartners to discuss payment levels under CarePartners' contract with the WUPN physicians. WUPN, through its management committee negotiators, demanded substantial price increases under the CarePartners contract. CarePartners counterproposed much smaller price increases, which WUPN rejected. WUPN insisted that CarePartners submit a revised price proposal by the end of February 2000 "that better addresses WUPN Member's [sic] expectations."
22. At a March 7, 2000, WUPN board meeting, the management committee reported that CarePartners submitted a revised proposal that was "equally as unacceptable as their first proposal," and the board rejected it. On April 4, the board voted to serve CarePartners with notice that WUPN was terminating its current contract, effective April 26. After receiving this notice, CarePartners – threatened with the community physicians' and faculty physicians' concerted refusal to deal – resumed contract negotiations with WUPN. On May 1, 2000, CarePartners agreed to pay the prices that WUPN demanded. The Board voted to accept these terms, which became effective December 1, 2000.

Negotiations with Other Payors

23. Pursuant to agreements with and among the community physicians and faculty physicians, and on their collective behalf, WUPN has negotiated price and other competitively

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significant contract terms with other payors as well, including CIGNA Healthcare, UnitedHealth Group, and Healthlink. WUPN's coercive tactics, including threatened refusals to deal, have forced payors to pay higher prices to WUPN member physicians to obtain their participation in the health insurance plans available to patients in the greater St. Louis area.

WUPN Engaged in Restraints of Trade

24. The faculty physicians and community physicians, acting as a combination of competing physicians through and with WUPN, have restrained competition by, among other things:
 - a. facilitating, negotiating, entering into, and implementing agreements among themselves and WUPN on price;
 - b. refusing to deal with payors except on collectively agreed-upon terms; and
 - c. negotiating prices and other competitively significant terms in contracts with payors.

WUPN's Actions Are Not Justified by Any Efficiencies

25. WUPN's joint negotiation of price and other competitively significant contract terms has not been, and is not, reasonably related to any efficiency-enhancing integration among the community physicians themselves, or among the community physicians jointly with the faculty physicians.

WUPN's Conduct Resulted in Anticompetitive Effects

26. WUPN's actions as described in this Complaint have had, or have tended to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the greater St. Louis area in the following ways, among others:

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- a. price and other forms of competition among WUPN's member physicians were unreasonably restrained;
 - b. prices for physician services were increased; and
 - c. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians.
27. The combinations, conspiracies, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combinations, conspiracies, acts, and practices, or the effects thereof, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-second day of August, 2003, issues its Complaint against WUPN.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of Washington University Physician Network (“WUPN”), hereinafter referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that Respondent has violated said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Washington University Physician Network is a not-for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of

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Missouri, with its office and principal place of business located at 7425 Forsyth Boulevard, Suite 307, Clayton, Missouri 63105.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means Washington University Physician Network, its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. “Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- C. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- D. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician services for itself or for any other person. Payor includes any person

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that develops, leases, or sells access to networks of physicians.

- E. “ Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- F. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- G. “Preexisting contract” means a contract that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by a Respondent, pursuant to Paragraph III.B. of this Order, of such payor’s right to terminate such contract.
- H. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- I. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 - 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.

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- J. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:
1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate jointly to control costs and improve quality by managing the provision of physician services such as risk-sharing involving:
 - a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity, or length of treatment, or other factors; and;
 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.

Decision and Order

- K. “WU faculty members” means Washington University School of Medicine (WUSM) employees or contracted providers who provide WU physician services.
- L. “WU physician services” means physician services provided by WU faculty members on behalf of WUSM, and for which WUSM receives all financial remuneration from the payor for the physician’s services.

II.

IT IS FURTHER ORDERED that Respondent, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 - 1. To negotiate on behalf of any physician with any payor;
 - 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 - 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 - 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent’s arrangements;

Decision and Order

- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal with a payor;
- C. Attempting to engage in any action prohibited by Paragraphs II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED HOWEVER, that nothing in Paragraph II shall prohibit any agreement involving, or conduct by, Respondent, that (A) is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically- integrated joint arrangement, so long as the arrangement does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement, or (B) solely involves WU faculty members with respect to WU physician services.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, send by first-class mail, with delivery confirmation, a copy of this Order and the Complaint to:
 - 1. each physician, except for WU faculty members, who participates, or has participated, in Respondent, that respondent has a record of having been in contact with since January 1, 1998, regarding contracting for the provision of physician services; and

Decision and Order

2. each officer, director, manager, and employee of Respondent;
- B. Within thirty (30) days after the date on which this Order becomes final, send by first-class mail, return receipt requested, copies of this Order, the Complaint, and the notice specified in Appendix A to this Order, to the chief executive officer of each payor that Respondent has a record of having been in contact with since January 1, 1998, regarding contracting for the provision of physician services;
- C. Terminate, without penalty or charge, in compliance with any applicable state laws, any preexisting contract between Respondent and any payor for the provision of physician services, upon receipt by Respondent of a written request from such payor to terminate such contract; and
- D. For a period of three (3) years after the date this Order becomes final:
1. Distribute by certified mail, return receipt requested, a copy of this Order and the Complaint to:
 - a. each physician who begins participating in Respondent, and who did not previously receive a copy of this Order and the Complaint, within thirty (30) days of the time that such participation begins;
 - b. each payor that contracts with Respondent for the provision of physician services, and that did not previously receive a copy of this Order and the Complaint, within thirty (30) days of the time that such payor enters into such contract; and
 - c. each person who becomes an officer, director, manager, or employee of Respondent, and who did not previously receive a copy of this Order and the

Decision and Order

Complaint, within thirty (30) days of the time that he or she assumes such responsibility; and

2. Annually publish a copy of this Order and the Complaint in an official annual report or newsletter sent to all physicians who participate in Respondent, with such prominence as is given to regularly featured articles.

IV.

IT IS FURTHER ORDERED that Respondent shall notify the Commission:

- A. At least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order; and
- B. Of any change in Respondent's principal address, within twenty (20) days of such change in address.

V.

IT IS FURTHER ORDERED that Respondent shall file verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth:

- A. In detail, the manner and form in which Respondent has complied and is complying with this Order;
- B. The name, address, and telephone number of each physician, medical group practice, and other group of physicians that Respondent has represented or advised

Decision and Order

with respect to their dealings with any payor in connection with the provision of physician services;

- C. The name, address, and telephone number of each payor with which Respondent has dealt while representing any physician, medical group practice, or other group of physicians in connection with the provision of physician services;
- D. Any actions taken in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement provided for in Paragraph II of this Order; and
- E. Any arrangement under which Respondent would act as an intermediary or agent on behalf of any physicians with health plans regarding contracts under which physicians would be compensated for the provision of physician services.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondent, and in the presence of counsel, and without restraint or interference from it, to interview Respondent or employees of Respondent.

Decision and Order

VII.

IT IS FURTHER ORDERED that this Order shall terminate on August 22, 2023.

By the Commission, Commissioner Harbour not participating.

Decision and Order

Appendix A

[letterhead of WUPN]

[date]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against Washington University Physician Network ("WUPN").

Pursuant to Paragraph III.C. of the enclosed order, WUPN must allow you to terminate, upon written request, without any penalty or charge, any contracts with WUPN that were in effect prior to the receipt of this letter.

Any request either to terminate or to extend the contract should be made in writing, and sent to me at the following address:
[address].

Sincerely,

[Signature of President or CEO of WUPN]
President or CEO WUPN
Washington University Physician Network

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with the Washington University Physician Network (WUPN). The agreement settles charges that WUPN violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by orchestrating and implementing agreements among WUPN and its independent, community-based physician members (“community physicians”), and facilitating agreements among its community physicians and its Washington University School of Medicine full-time faculty physician members (“faculty physicians”), to fix prices and other terms on which they would deal with health plans, and to refuse to deal with such purchasers except on collectively-determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by WUPN that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint Allegations

WUPN consists of 900 faculty physicians and 600 community physicians who provide health care services in St. Louis, Missouri and four neighboring counties (“the greater St. Louis area”). WUPN was established in 1993 to facilitate, among competing

Analysis

physicians, collective bargaining with health plans in order to obtain more favorable reimbursement rates and other “very favorable terms when compared to contracts entered into on an individual basis or through another organization.”

WUPN is a not-for-profit corporation, and its sole legal member is Washington University (“WU”), also a non-profit entity. Section 4 of the FTC excludes certain types of non-profit corporations from its definition of entities under its jurisdiction. However, the Commission has jurisdiction over WUPN because WUPN’s community physicians, who operate for profit, are “members” of WUPN due to their significant role in governing the organization. Also, WUPN provides substantial economic benefits for its community physician members, who make up a minority of the membership but are granted a substantial role in WUPN to enhance their incomes and bargaining power.

WUPN is managed and controlled by a Board of Directors made up of 16 community physicians and 13 faculty physicians. Contracts with health plans are negotiated by representatives of WUPN’s Management Committee, and progress of its negotiations is reported to WUPN’s Board. The Committee recommends to the Board whether to accept or reject a payor’s fee schedule, or whether to terminate or extend a payor’s existing contract. The Board votes on the recommendation, which requires majority approval.

WUPN has successfully coerced a number of health plans to increase the fees they pay to WUPN members, and thereby raised the cost of medical care in the greater St. Louis area. As a result of the challenged actions of WUPN, consumers in the greater St. Louis area are deprived of the benefits of competition among physicians. By facilitating agreements among WUPN members to deal only on collectively-determined terms, and actual or threatened refusals to deal with health plans that would not meet those terms, WUPN has violated Section 5 of the FTC Act.

Analysis

WUPN's collective negotiations with payors are not justified by any efficiency-enhancing integration among the community physicians, or among the community physicians and the faculty physicians.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of the illegal conduct charged in the complaint, while allowing WUPN to engage in legitimate conduct that does not impair competition. It is similar to recent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise the fees they receive from health plans.

The proposed order's specific provisions are as follows:

Paragraph II.A prohibits WUPN from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than WUPN.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits WUPN from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D proscribes inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

As in other orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations.

First, WUPN would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate

Analysis

joint contracting arrangements among competing physicians, whether a “qualified risk-sharing joint arrangement” or a “qualified clinically-integrated joint arrangement.” Second, WUPN would be permitted to enter into any agreement or engage in any conduct that only involves WU faculty members with respect to services provided by WU physicians.

As defined in the proposed order, a “qualified risk-sharing joint arrangement” possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the participants to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A “qualified clinically-integrated joint arrangement,” on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraphs III.A and III.B require WUPN to send notice of the order and complaint to all WUPN participating physicians, WUPN employees and principals, and all payors WUPN has contacted since January 1, 1998, concerning the provision of physician services. Paragraph III.C. requires WUPN to terminate, without penalty, any preexisting contract with a payor upon receipt of a payor’s written request to terminate the contract. This provision is intended to eliminate the effects of WUPN’s anticompetitive actions. Paragraph III.D of the proposed order

Analysis

requires WUPN to distribute the order and complaint prospectively to new members, newly contracted payors, and new employees for a period of three years, and Paragraphs IV through VI set out WUPN's requirements to report or provide access to information to the Commission to facilitate monitoring of WUPN's compliance with the order.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

GLOBAL INSTRUMENTS LTD., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4092; File No. 0223122*
Complaint, August 22, 2003--Decision, August 22, 2003

This consent order, among other things, prohibits Respondents Global Instruments Ltd. and Charles Patterson from representing – unless they possess competent and reliable scientific evidence that substantiates the representations – (1) that any pest control product repels, controls, or eliminates, temporarily or indefinitely, mice, rats, cockroaches, or any other insects or animal pests and that it does so in an area of a certain size; (2) that any pest control product is an effective alternative to or eliminates the need for chemicals, pesticides, insecticides, exterminators, or any other pest control product or service; and (3) that any pest control product will alter the electromagnetic field, send a pulsating signal, or otherwise work inside the walls or through the wiring of homes or other buildings in a manner that effectively repels, controls, drives away, or eliminates mice, rats, cockroaches, or any other insects or animal pests. The order also requires the respondents to possess and rely upon competent and reliable evidence – which when appropriate must be competent and reliable scientific evidence – for claims about the benefit, performance, or efficacy of any product.

Participants

For the Commission: *Constance M. Vecellio, Janice Podoll Frankle, Patricia F. Bak, Robert M. Frisby, Elaine D. Kolish and Susan Braman.*

For the Respondents: *Stan Johnston, Lewis, Rice & Fingersh, L.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Global Instruments Ltd., a corporation, and Charles Patterson, individually and as an officer of the corporation (“respondents”), have violated the provisions of the Federal Trade Commission

Complaint

Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Global Instruments Ltd. is an Iowa corporation with its principal office or place of business at 819 Industrial Drive, Trenton, Missouri 64683.

2. Respondent Charles Patterson is President of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the corporation, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Global Instruments Ltd.

3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

Electromagnetic Pest-Control Products

4. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed electromagnetic pest-control products to the public, including the Pest-A-Cator and the Pest-A-Cator Too! (collectively, “Pest-A-Cator Products”) and Riddex and Riddex Jr. (collectively, “Riddex Products”).

5. Respondents have disseminated or have caused to be disseminated advertisements for the Pest-A-Cator Products and Riddex Products, including but not necessarily limited to the attached Exhibits A through I. These advertisements contain the following statements:

- A. “PEST-A-CATOR
- Works on mice, rats, and roaches. . . .
 - Guaranteed, or your money back!
 - Works in standard size homes up to 2000 square feet.
- . . .

Complaint

- Fast working - infested areas will be noticeably [sic] clean in 2 - 4 weeks.

...

- Helps in reducing monthly exterminator costs.”
(www.global-instruments.com/pest-a-cator.html) (6/4/02)
[Exhibit A]

B. “Pest-A-Cator: The eliminator, not the imitator!

- Guaranteed on mice, rats and roaches.

...

Up to 2,000 sq. ft.

Pest-A-Cator is great for homes, office buildings, schools, restaurants, hospitals, etc.

...

Rodent & Insect Repeller

The Ultimate Power in Electronic Pest Control

GUARANTEED!”

(Pest-A-Cator and Pest-A-Cator Plus Brochure—available on website) [Exhibit B]

C. “Pest-A-Cator Too!

Up to 1,000 sq. ft.

Pest-A-Cator Too! is great for smaller homes, condominiums, apartments, mobile homes, etc.”

(Pest-A-Cator and Pest-A-Cator Plus Brochure—available on website) [Exhibit B]

D. “This is not one of those ‘sonic’ noise machines. They only work in one room at a time! Pest-A-Cator uses the household wiring to turn the whole place into one huge pest-irritating machine which forces pests (mice, rats, roaches) to leave the premises. Pest-A-Cator is the alternative to those harmful or hazardous chemicals, pesticides and insecticides which can harm children, family pets, friends, the environment and more.

...

A single Pest-A-Cator will aid in ridding most standard 2,000 sq. ft. areas of mice, rats and roaches, all within 2-4

Complaint

weeks and all without the aid of chemicals and the need for costly exterminators. The unit sends a pulsating signal throughout the wiring of the home annoying insects and rodents, driving them from behind the walls, out of cabinets and from under sinks where they hide and nest.

Just plug the Pest-A-Cator into any 110V outlet and let it work – 24 hours a day, 365 days a year.

...

Your optimum goal for an electronic pest control device is to eliminate the problem. Pest control problems are eliminated when the solution strikes at the nesting areas, which are in the walls, cabinets and under the sinks. Pest-A-Cator was designed to send a pulsating signal throughout the wiring of the home annoying insects and rodents, driving them from behind the walls, out of cabinets and from under sinks where they hide and nest.”

(Pest-A-Cator and Pest-A-Cator Plus Brochure—available on website) [Exhibit B]

E. “Pest-A-Cator

Don’t drive pests into hiding. Drive them out. . . Drive them away.

...

‘The Pest-A-Cator turns your house wiring into a giant pest repeller!’

. . . The *Pest-A-Cator* uses the wiring in your home to turn the whole place into one huge, pest irritating machine which forces them to leave the premises.

...

The unique activity sends a pulsating signal throughout the wiring of homes, businesses and other structures. This silent pulse annoys insects and rodents, driving them out from behind walls, floors and ceilings where they hide and nest.

...

- Reduces monthly pest control visits.
- Tested by the U.S. Navy and in public housing facilities.

...

Complaint

The Pest-A-Cator is cost effective. A 1,500 square foot, 8 room house will cost a consumer the price of one unit.” (Pest-A-Cator, Pest-A-Cator Plus and PestVacator Product Brochure) [Exhibit C]

F. “Pest-A-Cator Too

- Specially designed for smaller living quarters such as apartments, condominiums, mobile homes, etc. . . .
- Works on mice, rats, and roaches . . . Guaranteed or your money back!
- Works in areas up to 1,000 square feet. . . .
- Fast working! Infested areas will be noticeably [sic] clean in 2 - 4 weeks.”
(www.global-instruments.com/pest-a-cator2.html)
(6/4/02) [Exhibit D]

G. **“1. HOW DOES IT WORK?”**

Pest-A-Cator is NOT an ultrasonic product. It works with the electrical wiring in your home. The electrical wiring inside your home already has an existing field surrounding it. Pest-A-Cator, when plugged in, pulses this field. It doesn’t really add to or take away from the field, just pulses it. Rats, mice, and cockroaches like to live and nest inside the walls. They feel this and don’t like it and it drives them out. This means that if there is an infestation of rats, mice or roaches, the consumer WILL see more during the first four weeks or so, because it is driving them out of the walls. We recommend using traps, glue boards, etc. the first few weeks to help clean up the initial problem.

...

6. WHAT IS IT GUARANTEED TO WORK ON?

Rats, Mice and Cockroaches ONLY! Consumer testimonials state that it works on ants, spiders, crickets, etc., but we do NOT guarantee it to work on these pests.

...

Complaint

8. WILL I EVER SEE A PEST AFTER PLUGGING IN THE PEST-A-CATOR?

Consumers may still see an occasional rat, mouse or cockroach that has wandered in, but they will not stay and take up residency in the home after a Pest-A-Cator is plugged in. If they can, they will leave the same way they came in.”(www.global-instruments.com/faq.html) (6/5/02)
[Exhibit E]

- H. “A single Pest-A-Cator unit will aid in ridding most standard 2,000 square foot areas of mice, rats and roaches within 2-4 weeks. The unique activity sends a pulsating signal throughout the wiring of homes, businesses and other structures. This silent pulse annoys insects and rodents, driving them out from behind walls, floors and ceilings where they hide and nest.”
Just plug the *Pest-A-Cator* into any 110 outlet and let it go to work.”
(www.global-instruments.com/how it works.html) (6/5/02)
[Exhibit F]
- I. MALE ANNOUNCER: “. . . Introducing a revolutionary unit that rids homes of roaches, rats and mice without toxic chemicals, harmful side effects, unsightly boxes or high monthly fees.”
ON SCREEN: Pest-A-Cator product
MALE ANNOUNCER: “Introducing the Pest-A-Cator, the safe and effective way to get rid of these pests once and for all.”
. . .
MALE ANNOUNCER: “This innovative technology drives rodents and roaches out of your home and it’s completely safe for humans, as well as cats, dogs and fish.”
. . .
MALE ANNOUNCER: “It starts to work immediately by altering the normal field around your wiring, creating an environment that aids in the control of mice, rats and roaches where the problem exists, in the walls and ceilings.”

Complaint

ON SCREEN: Animation of pests leaving home
(Television commercial) (date unknown) [Exhibit G]

- J. MALE ANNOUNCER: “It takes two to four weeks to take care of normal pest and rodent problems.”
ON SCREEN: “Allow 2-4 weeks for infestations”
MALE ANNOUNCER: “Then your problem will be gone – and won’t come back as long as the unit is plugged in.”
ON SCREEN: “Problem Gone!”
MALE ANNOUNCER: “-- and won’t come back as long as the unit is plugged in.”
ON SCREEN: “PEST-A-CATOR product
No Harmful Chemicals. Today’s Pest Control.
Don’t drive pests into hiding?
Drive them out . . .
Drive them away.”
(Television commercial) (date unknown) [Exhibit H]

- K. “Introducing **RIDDEX**
‘The Environmental Alternative For Safer Pest Control’
Want to reduce the use of hazardous chemicals (insecticides and pesticides) in your everyday life, around children, and food products?
. . .
Just plug in the ‘**RIDDEX**’ to a standard 110 or 220 volt outlet and this new technology starts working by altering the normal field around your wiring, creating an environment that aids in the control of mice, rats, and roaches in the walls and ceiling where your problem exists.
House wiring turns your home into a giant pest repeller!
- Makes your home Pest-Free without harmful chemicals.
 - Uses electrical wiring in the walls to drive pests away from homes, hotels, motels, offices, restaurants and mobile homes.
 - Environmental Alternative.
 - No need for pest control services.
- . . .
- One unit takes care of an average home (2,000 sq. ft.)

Complaint

...

DRIVES OUT ROACHES RODENTS INSECTS &
OTHER PESTS

...

Allow two to four weeks for satisfactory results.
(RIDDEX Brochure) [Exhibit I]

6. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that:
 - A. Pest-A-Cator Products and Riddex Products effectively repel, drive away or eliminate mice, rats, and cockroaches from users' homes, office buildings, restaurants and other buildings in two to four weeks;
 - B. One Pest-A-Cator unit effectively repels, drives away or eliminates mice, rats, and cockroaches throughout standard size homes up to 2,000 square feet;
 - C. One Pest-A-Cator Too! unit effectively repels, drives away or eliminates mice, rats, and cockroaches throughout smaller homes, condominiums, apartments, and mobile homes up to 1,000 square feet;
 - D. One Riddex unit effectively repels, drives away or eliminates mice, rats, and cockroaches throughout homes up to 2,000 square feet;
 - E. Pest-A-Cator Products and Riddex Products are an effective alternative to or eliminate the need for chemicals, pesticides, insecticides, exterminators, and pest control services;
 - F. Pest-A-Cator Products send a pulsating signal throughout the electrical wiring inside homes, businesses and other structures in a manner that drives mice, rats, and cockroaches out from the nesting areas in the walls, floors, ceilings, cabinets, and under sinks;

Complaint

- G. After using the Pest-A-Cator for two to four weeks, pests and rodents will be gone and will not return as long as the unit stays plugged in; and
 - H. Riddex Products alter the field around electrical wiring inside homes, hotels, motels, offices, restaurants and mobile homes in a manner that drives mice, rats, and cockroaches out.
7. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.
8. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6 at the time the representations were made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

Pest-A-Cator Plus Products

9. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed combination electromagnetic and ultrasonic pest control products to the public, including the Pest-A-Cator Plus and the Pest-A-Cator Too! Plus (collectively, "Pest-A-Cator Plus Products").
10. Respondents have disseminated or have caused to be disseminated advertisements for the Pest-A-Cator Plus Products, including but not necessarily limited to the attached Exhibits C, J, and K. These advertisements contain the following statements:
- A. "Electronic Pest Control Just Got Better! Introducing PEST-A-CATOR Plus Patented 'Pulse' technology Plus

Complaint

Ultrasonic Technology creates the ultimate power in electronic pest control! GUARANTEED!

...

Pest-A-Cator Plus products are the best of both worlds!

Why? Because it [sic] has two technologies integrated into one product that's effective in repelling pests from the entire home. Pulse or electro-magnetic technology works through the household wiring to upset nesting sites of mice, rats and roaches within walls, ceilings and floors. Ultrasonic technology controls a variety of pests (rodents, insects, spiders, bats, etc.) in open areas that have a high rate of visual activity. . . .

Pest-A-Cator Plus and Pest-A-Cator Too! Plus products are great to use in homes, office buildings, schools, restaurants, hospitals, etc.

...

Pest-A-Cator Plus – Up to 2,000 sq. ft.

...

Pest-A-Cator Too! Plus – Up to 1,000 sq. ft.”

(Pest-A-Cator, Pest-A-Cator Plus, and PestVacator Product Brochure) [Exhibit C]

B. “Pest-A-Cator Plus

Patented ‘Pulse’ technology PLUS Ultrasonic Technology creates the ultimate power in electronic pest control!

- Only 1 unit needed per Average home of 2000 sq. ft.

...

2 TECHNOLOGIES IN 1!

‘Pulse Technology’

- State of the art technology controls pest [sic] deep within the walls, ceilings and floors.
- Guaranteed to aid with controlling on [sic] mice, rats and roaches.
- Highly effective in areas up to 2,000 sq. ft. and up to 1,000 sq. ft. with Pest-A-Cator Too Plus

‘Ultrasonic’ Technology’

...

Complaint

- Ultrasonic sound waves continue to bounce throughout the unobstructed room to aid with the control of pests on a continual basis.
- Aids in controlling rodents & insects (i.e. spiders, silverfish, etc.)”

(www.global-instruments.com/pest-a-catorplus.html)

(6/5/02) [Exhibit J]

C. “Pest-A-Cator Too! Plus

- Recommended for apartments, condominiums, multi-family and [sic] structures 1000 sq. ft. or less.

...

- Highly effective in areas up to 1,000 sq. ft. . . .”
(www.global-instruments.com/pest-a-catorplus_2.html)
(6/5/02) [Exhibit K]

11. Through the means described in Paragraph 10, respondents have represented, expressly or by implication that:
- A. Pest-A-Cator Plus Products’ pulse or electromagnetic technology works or pulsates through the household wiring to upset nesting sites of mice, rats, and cockroaches within walls, ceilings, and floors;
 - B. Pest-A-Cator Plus Products effectively repel, control, or eliminate mice, rats, cockroaches, rodents, insects, spiders, silverfish, and bats from homes, office buildings, schools, restaurants, and hospitals;
 - C. One Pest-A-Cator Plus unit effectively repels, controls, or eliminates mice, rats, cockroaches, rodents, insects, spiders, silverfish, and bats from homes, office buildings, schools, restaurants, and hospitals up to 2,000 square feet; and
 - D. One Pest-A-Cator Too! Plus unit effectively repels, controls, or eliminates mice, rats, cockroaches, rodents, insects, spiders, silverfish, and bats from apartments,

Complaint

condominiums, and multi-family structures up to 1,000 square feet.

12. Through the means described in Paragraph 10, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 11, at the time the representations were made.
13. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 11, at the time the representations were made. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

PestVacator Products

14. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed ultrasonic pest control products to the public, including the PestVacator 800 and PestVacator 1500 (collectively, "PestVacator Products").
15. Respondents have disseminated or have caused to be disseminated advertisements for PestVacator Products, including but not necessarily limited to the attached Exhibits C and L. These advertisements contain the following statements:
 - A. "PestVacator's ultrasonic technology is a safe and humane way to drive household pests (mice, rats, bats, crickets, spiders and other insects) away from your home including attics, basements and crawl spaces. Most household pests hear sounds far above the range of human hearing. Having no ability to adapt to these annoying sounds, they will leave the protected area for a more comfortable living area, most often outdoors.
...
PestVacator electronic pest control products; The friendly and effective alternative to using chemicals & traps.

Complaint

PestVacator will aid in ridding your home of insects and rodents by using safe and powerful ultrasonic signals which penetrate the nervous systems of these pests, yet are undetectable to humans and common household pets.

Model PV800

...

- Protects areas up to 800 sq. ft.

...

Model PV1500

...

Same attributes as the PV800 but works in areas up to 1500 sq. ft.”

(Pest-A-Cator, Pest-A-Cator Plus, and PestVacator Product Brochure) [Exhibit C]

- B. “PestVacator Electronic Insect & Rodent Repeller
- Ultrasonic Technology
 - Aids in ridding the protected area of unwanted pests – up to 800 Sq. Ft. of protection!”
- ...
- No toxic chemicals, posions [sic] or traps needed.”
(www.global-instruments.com/pv800html) (6/3/02)
[Exhibit L]
16. Through the means described in Paragraph 15, respondents have represented, expressly or by implication, that:
- A. PestVacator Products effectively repel, drive away or eliminate mice, rats, bats, crickets, spiders, and other insects from the user’s home, including attics, basements and crawl spaces;
- B. One Pest Vacator 800 effectively repels, drives away or eliminates mice, rats, bats, crickets, spiders, and other insects from the user’s home, including attics, basements and crawl spaces, up to 800 square feet;

Complaint

- C. One PestVacator 1500 effectively repels, drives away or eliminates mice, rats, bats, crickets, spiders, and other insects from the user's home, including attics, basements and crawl spaces, up to 1500 square feet; and
 - D. PestVacator Products eliminate the need for toxic chemicals, poisons, or traps.
17. Through the means described in Paragraph 15, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 16, at the time the representations were made.
18. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 16, at the time the representations were made. Therefore, the representation set forth in Paragraph 17 was, and is, false or misleading.
19. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-second day of August, 2003, has issued this complaint against respondents.

By the Commission, Commissioner Harbour not participating.



Global Instruments Ltd.

[Home](#)

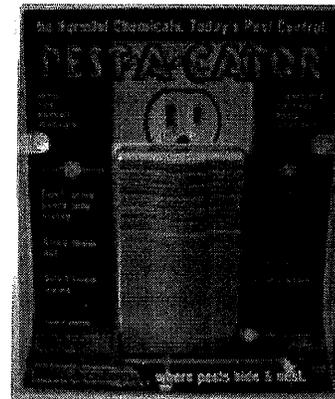
PRODUCTS

- [Pest-A-Cator](#)
- [Pest-A-Cator Too](#)
- [Pest-A-Cator Plus](#)
- [Pest-A-Cator Too Plus](#)
- [PestVacator 800](#)
- [PestVacator 1500](#)

-
- [Frequently Asked Questions](#)
 - [How it works](#)
 - [Suggestions for best results](#)
 - [Company History](#)

-
- [Dealers](#)
 - [Testimonials](#)
 - [Contact Us](#)

PEST-A-CATOR



[PDF Brochure](#)
[Advertising Photos](#)

- Works on mice, rats, and roaches.....
Guaranteed, or your money back!
- Works in standard size homes up to 2000 square feet. Multiple units are needed in larger areas or multiple stories.
- Fast working - infested areas will be noticeably clean in 2 - 4 weeks.
- Direct plug-in feature is user friendly and does not have to be plugged in plain view of infested areas.
- Safe to use around children and household pets (except rodent type pets).
- Helps in reducing monthly exterminator costs.
- Backed by a 60-day money back guarantee and a 1-year warranty on parts and workmanship.
- Another quality product manufactured in the USA

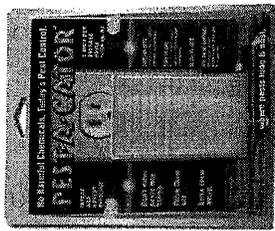
[Home](#) | [Pest-A-Cator](#) | [Pest-A-Cator Too](#) | [Pest-A-Cator Plus](#) | [Pest-A-Cator Too Plus](#) | [PestVacator 800](#) | [PestVacator 1500](#) | [Frequently Asked Questions](#) | [How it works](#) | [Contact](#) | [Company History](#) | [Dealers](#) | [Testimonials](#)

Exhibit A

Easy to use...Just plug it in!

Pest-A-Cator: The eliminator, not the imitator!

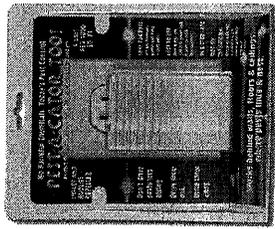
Pest-A-Cator



Up to 2,000 sq. ft.

Pest-A-Cator is great for homes, office buildings, schools, restaurants, hospitals, etc.

Pest-A-Cator Too!



Up to 1,000 sq. ft.

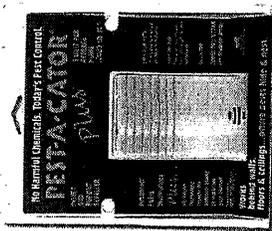
Pest-A-Cator Too! is great for smaller homes, condominiums, apartments, mobile homes, etc.

- Guaranteed on mice, rats and roaches. Call Customer Service or visit our website for more ideas and complete instructions.
- Direct plug-in feature is easy to use. Just plug into any 110V outlet.
- Safe around children and household pets, except rodent type pets.
- Continues to reduce the cost of chemicals, baits and traps for years!

Safe for all pets except spiders, hamsters, gerbils, and other rodent pets

The ultimate power in electronic pest control!

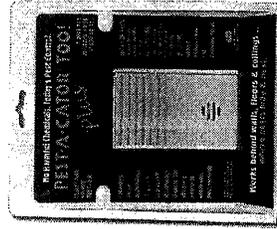
Pest-A-Cator Plus



Up to 2,000 sq. ft.

Pest-A-Cator Plus is great for homes, office buildings, schools, restaurants, hospitals, etc.

Pest-A-Cator Too! Plus

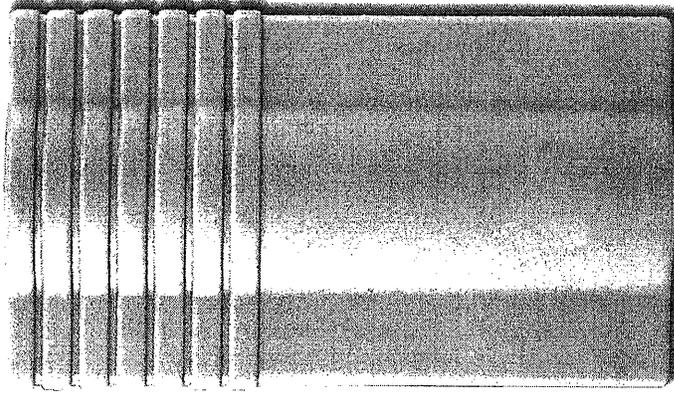


Up to 1,000 sq. ft.

Pest-A-Cator Too! Plus is great for smaller homes, condominiums, apartments, mobile homes, etc.

- *Two Technologies in ONE!*
- "Pulse" technology uses the household wiring to drive mice, rats and roaches from the walls.
- Ultrasonic technology controls a variety of pests (rodents, insects, spiders, bats, etc.) in those areas that have a high rate of visual activity.
- Direct plug-in feature is easy to use.
- Completely maintenance-free! Not a chemical that washes away, not a trap that requires emptying dead or dying animals.

PEST-A-CATOR®
by Global Instruments, Ltd.



Rodent & Insect Repeller

**The Ultimate Power in
Electronic Pest Control
GUARANTEED!**

www.pestacator.com

PEST-A-CATOR®
by Global Instruments, Ltd.



Pest-A-Cator and Pest-A-Cator Plus
are proud to be
Made in the USA

USA Patent #4,802,057
German Patent #8909186.8
Other patents pending

EPA Est. No. 053990-MO-001



Insect and
Rodent Control
Equipment
Control Number 29U4

Global Instruments, Ltd.
819 Industrial Drive
Trenton, MO 64683

For Customer Service Call
800-338-5028
or email us at

customerservice@global-instruments.com

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Chemicals, baits, traps, exterminators... All are costly and are they the most effective sources today?

*Dear Global Instruments,
Well the rats are gone and so are
the mice. I am so happy! For years I
have been plagued by rodents and
they have been winning. NO MORE!
The Pest-A-Cator is a good thing. I
will tell my friends!*

Does this story sound familiar? Believe it or not, there are hundreds more like it and now there's a happy ending just waiting for your tale!

Introducing:

PEST-A-CATOR®

Imagine fingernails on the blackboard 24 hours a day! Well, that kind of irritation is the theory behind the Pest-A-Cator pest control device from Global Instruments. This is not one of those "sonic" noise machines. They only work in one room at a time! Pest-A-Cator uses the household wiring to turn the whole place into one huge pest-irritating machine which forces pests (mice, rats, roaches) to leave the premises.

Pest-A-Cator is the alternative to those harmful or hazardous chemicals, pesticides and insecticides which can harm children, family pets, friends, the environment and more. And what about the pest control company that visits every month? Do you know exactly what that chemical is they're spraying around the house and what it's doing to your family?

This is where your happy ending starts! A single Pest-A-Cator will aid in ridding most standard 2,000 sq. ft. areas of mice, rats and roaches, all within 2-4 weeks and all without the aid of chemicals and the need for costly exterminators. The unit sends a pulsating signal throughout the wiring of the home annoying insects and rodents, driving them from behind the walls, out of cabinets and from under sinks where they hide and nest.

Just plug the Pest-A-Cator into any 110V outlet and let it work—24 hours a day, 365 days a year. The cost is less than a 4-watt night light and it won't affect computers, T.V.'s or other appliances. It's recommended that multiple units be used in multiple story structures and in areas that are larger than the prescribed Pest-A-Cator unit.

We strongly recommend continuous use to prevent re-infestation. Pest-A-Cator products are safe to use around household pets except rodent and spider pets.

Money Back Guarantee!

Again, we suggest 2-4 weeks for satisfactory results. If you are not satisfied with the results of this product within 60 days, just return the undamaged unit along with the purchase receipt to the place of purchase for a full refund.

Pest-A-Cator is also backed by a one year warranty on all parts and workmanship.

What's your goal when choosing between electronic pest control products?

Your optimum goal for an electronic pest control device is to eliminate the problem. Pest control problems are eliminated when the solution strikes at the nesting areas, which are in the walls, cabinets and under the sinks.

Pest-A-Cator was designed to send a pulsating signal throughout the wiring of the home annoying insects and rodents, driving them from behind the walls, out of cabinets and from under sinks where they hide and nest.

You may be enticed to purchase one of the lower priced traditional ultrasonic products.

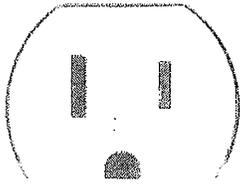
These devices manage a variety of spaces one room at a time and the sound wave bounces off hard surfaces (See comparison below). The areas must be obstruction free to be completely effective. What does this mean? It means that the product will be the most effective when there isn't any furniture or anything else that will deter the signal. It also means that if you have a problem in hidden spaces, ultrasonic sound waves will not reach these infested areas at all.

Pest-A-Cator vs. Traditional Ultrasonic Products Scenario—10 rooms, 2,000 sq. ft. home, each room 12' x 15'

	PEST-A-CATOR	ULTRASONICS
Marketed Coverage Area	2,000 sq. ft.	2,000 sq. ft.
Maximum coverage per unit (based on the scenario)	2,000 sq. ft.	180 sq. ft.
Maximum number of rooms covered?	ALL	1
Does the signal reach in the walls?	YES	No
Does the signal reach in the cabinets?	YES	No
Does the signal reach under sinks?	YES	No

PEST-A-CATOR[®]

No Harmful Chemicals. Today's Pest Control[™]



Don't drive pests
into hiding.

Drive them out...

Drive them away.

Works against mice, rats and roaches.

Works behind walls, floors & ceilings...
Where pests hide & nest.

Not an ultrasonic product.

Exhibit C

PEST-A-CATOR®

No Harmful Chemicals Today's Pest Control™

"The Pest-A-Cator turns your house wiring into a giant pest repeller!"

"Imagine fingernails on the blackboard 24 hours a day!"

Well, that kind of irritation is the theory behind the *Pest-A-Cator* pest control device from Global Instruments. This is **not** one of those 'sonic' noise machines. The *Pest-A-Cator* uses the wiring in your home to turn the whole place into one huge, pest irritating machine which forces them to leave the premises.

Pest-A-Cator is the alternative to harmful or hazardous chemicals, pesticides and insecticides which can harm children, family pets*, friends, the environment and more. A single *Pest-A-Cator* unit will aid in ridding most standard 2,000 square foot areas of mice, rats and roaches within 2-4 weeks. The unique activity sends a pulsating signal throughout the wiring of homes, businesses and other structures. This silent pulse annoys insects and rodents, driving them out from behind walls, floors and ceilings where they hide and nest.

Just plug the *Pest-A-Cator* into any 110 outlet and let it go to work. One unit is all that is required for an average home up to 2,000 square feet. Additional units are needed for excess of 2,000 square feet or multiple story structures. The unique activity will not affect computers, telephones or other home appliances.

*Safe for all pets except hamsters, gerbils and other rodent pets.

- Chemical Free!
- Safe for Pets
- Protects up to 2,000 square feet
- User Friendly
- Clean and Maintenance Free
- Reduces monthly pest control visits.
- Tested by the U.S. Navy and in public housing facilities.
- U.L. Listed Safe

#2100 - Retail

#2140 - Counter Display

#2180 - Floor Display

#2200 - Mail Order

Pest-A-Cator is manufactured and distributed by Global Instruments. Global Instruments has distributed millions of electronic pest repelling products throughout the world which have been tested by the U.S. Navy and in public housing facilities. The *Pest-A-Cator* is great for homes, businesses, restaurants, hospitals and more. It is backed by a 60 day money back guarantee and a one year warranty on all parts and workmanship. The *Pest-A-Cator* is another quality product "Made in the U.S.A."

COMPARE

The Pest-A-Cator works behind walls, floors and ceilings where pests hide and nest. Only one unit is needed per 2,000 square feet.

1. Ultrasonic products manage one room at a time.
2. Rooms must be obstruction free.
3. Ultrasonics will not penetrate walls, floors, ceilings or furniture or go around corners.

The Pest-A-Cator sends a pulsating signal through your entire home causing pests to leave the premises within 2 - 4 weeks.

Ultrasonic products have a sound wave that only annoys pests and drives them into hiding still within your house. More of an "out of sight, out of mind" mentality.

The Pest-A-Cator is cost effective. A 1,500 square foot, 8 room house will cost a consumer the price of one unit.

Ultrasonic products in a 1,500 square foot house with 8 rooms would cost a consumer approximately \$200.00 (average \$25.00 per unit).

Electronic Pest Control Just Got Better!

Introducing

PEST-A-CATOR *Plus*

**Patented "Pulse"
technology**

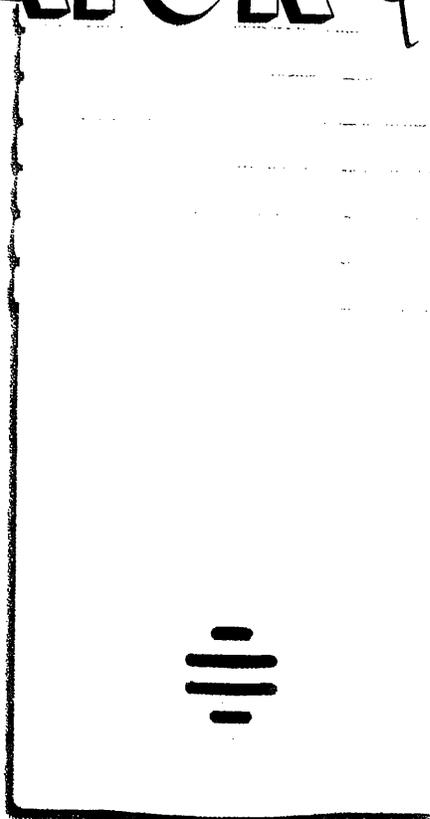
Plus

**Ultrasonic Technology
creates the ultimate
power in electronic
pest control!
GUARANTEED!**



Made in the USA

**For More Information,
Call 800-338-5028**



- Direct plug-in feature is easy to use. Just plug the device into any 110V outlet.
- Safe around children & household pets (except rodent & spider type pets).
- Completely maintenance-free! Not a chemical that washes away, not a trap that requires emptying of dead or dying animals.
- Backed by a 60-day money back guarantee!

2 TECHNOLOGIES IN 1!

"Pulse" Technology

- State of the art technology controls pests deep within the walls, ceilings and floors.
- Guaranteed to work on mice, rats and roaches.
- Highly effective in areas up to 2,000 sq. ft. and up to 1,000 sq. ft. with Pest-A-Cator Too Plus.
- Global Instruments patented technology.

"Ultrasonic" Technology

- Older technology controls pests in problem areas.
- Ultrasonic sound waves continue to bounce throughout the unobstructed room to control pests on a continual basis.
- Aids in controlling rodents & insects (i.e. spiders, fleas, silverfish, etc.)

Pest-A-Cator Plus - The best of both worlds!

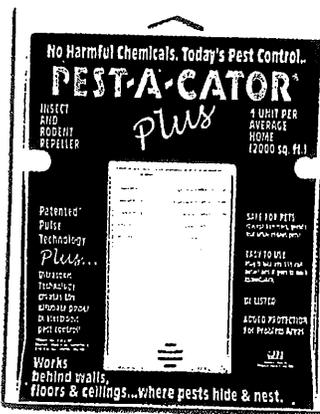
Pest-A-Cator Plus products are the best of both worlds! Why? Because it has two technologies integrated into one product that's effective in repelling pests from the entire home. Pulse or electro-magnetic technology works through the household wiring to upset nesting sites of mice, rats and roaches within walls, ceilings and floors. Ultrasonic technology controls a variety of pests (rodents, insects, spiders, bats, etc.) in open

areas that have a high rate of visual activity. Although the product won't harm standard household pets, it's strongly recommended not to be used around rodent and spider pets.

Pest-A-Cator Plus and Pest-A-Cator Tool Plus products are great to use in homes, office buildings, schools, restaurants, hospitals, etc.

Product Information

Pest-A-Cator Plus



Up to 2,000 sq. ft.

UPC #50903257506
 #12100-Bulk Product
 #12140-Counter Display
 #12180-Floor Display
 #12200-Mail Order

Sell Through Products

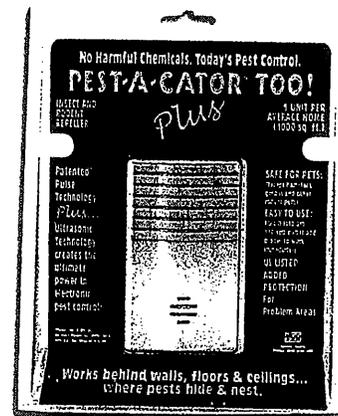
Customer Brochures Product Video
 Merchandising FAQ's
 Displays

USA Patent #4,802,057
 German Patent #8909186.8
 Other patents pending
 EPA Est. No. 053390-MO-001



Insect and
 Rodent Control
 Equipment
 Control Number 29U4

Pest-A-Cator Tool Plus



Up to 1,000 sq. ft.

UPC #50903257605
 #11100-Bulk Product
 #11140-Counter Display
 #11180-Floor Display
 #11200-Mail Order

MONEY BACK GUARANTEE

Global Instruments Ltd. guarantees customer satisfaction. If not satisfied with results within 60 days, return the undamaged unit and the receipt to the place of purchase for a full refund. Pest-A-Cator Plus products are backed by a 1-year limited warranty on all parts and workmanship.

For Customer Service, call 800-338-5028 or email us at customerservice@global-instruments.com

Phone: 660-359-4398
 Fax: 660-359-5031

Manufactured by
Global Instruments Ltd.
 Trenton, Missouri 64683

Check us out on the web
www.pestacator.com

PestVacator[®]

Electronic Insect & Rodent Repeller

PestVacator's ultrasonic technology is a safe and humane way to drive household pests (mice, rats, bats, crickets, spiders and other insects) away from your home including attics, basements and crawl spaces.

Most household pests hear sounds far above the range of human hearing. Having no ability to adapt to these annoying sounds, they will leave the protected area for a more comfortable living area, most often outdoors.

Safe and Powerful

Ultrasonic

Protection Against

Insects & Rodents

PestVacator Features and Benefits

- Available in two sizes (800 sq. ft. and 1,500 sq. ft.)
- Aids in ridding the protected area of unwanted pests
- Promotes healthier family living environments
- Silently protects areas 24-hours a day, 365 days a year
- No toxic chemicals, poisons or traps needed and costs pennies a day to operate
- Safe for household pets (except rodent and spider pets)
- For maximum effectiveness, combine efforts with Global Instrument's Pest-A-Cator products.

For more information call:
1-800-338-5028

PestVacator[®] and Pest-A-Cator[®] are trademarks of Global Instruments, Ltd. Trenton MO

PestVacator electronic pest control products; The friendly and effective alternative to using chemicals & traps.

PestVacator will aid in ridding your home of insects and rodents by using safe and powerful ultrasonic signals which penetrate the nervous systems of these pests, yet are undetectable to humans and common household pets.

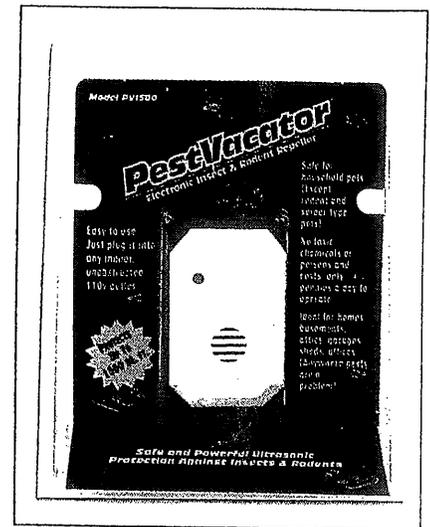
PestVacator Products

Model PV800

- UPC #50903008009
- Protects areas up to 800 sq. ft.
- Direct plug-in feature is easy to use
- Multiple units are needed in larger areas or multiple rooms

Model PV1500

- UPC #50903015007
- Same attributes as the PV800 but works in areas up to 1,500 sq. ft.
- Works great in large unobstructed rooms (i.e. attics, basements, 3-car garages, warehouses, etc.)
- Great for combining efforts with Pest-A-Cator products



Limited Warranty

PestVacator is backed by a one year limited warranty on all parts and workmanship. If the unit fails to operate during the warranty period, return it to the place of purchase along with your purchase receipt.

PestVacator complies with part 15 of the FCC rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interferences that may cause undesired operation.

**For Customer Service, call 800-338-5028 or
email us at customerservice@global-instruments.com**

Phone: 660-359-4398

Fax: 660-359-5031

Check us out on the web

www.global-instruments.com

Manufactured for

Global Instruments Ltd.

Trenton, Missouri 64683



Insect and
Rodent Control
Equipment
Control Number 29U4

EPA Est. No. 053390-MO-001
Assembled in Mexico



No Harmful Chemicals.
Today's Pest Control™

PEST-A-CATOR® TOO!

Perfect for condominiums, apartments, small homes and offices.

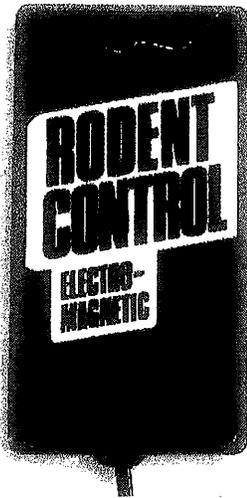
The Pest-A-Cator Too! has all of the same great features as the *Pest-A-Cator* but is made for areas of 1000 square feet or less such as apartments, condominiums, offices and small homes. Packaged in a molded plastic clamshell to be hung for display.

- #1100 - Retail
- #1140 - Counter Display
- #1180 - Floor Display
- #1200 - Mail Order

POTENTIAL MARKET

Estimated 80 million households representing \$3.2 billion in retail sales.

RODENT CONTROL

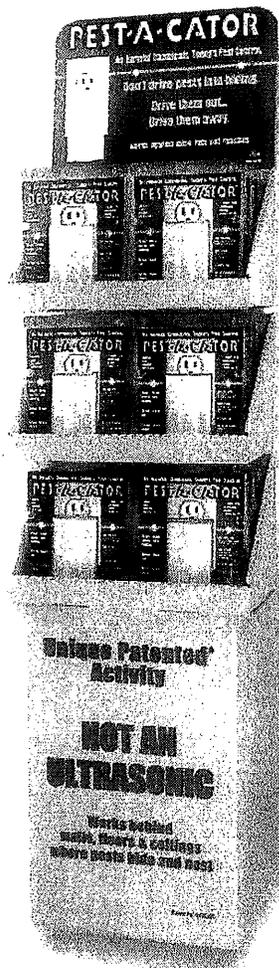


#3300

The Rodent Control device is designed to protect engines, electrical wiring, and vehicle interiors from rodent gnawing damage. Don't stop there. The variety of uses become limitless.

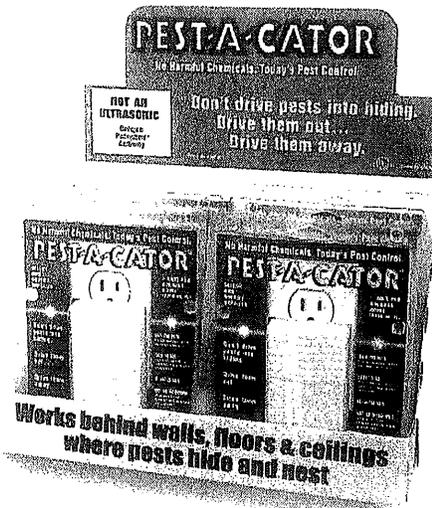
The magnetic device sends the pulsating signal through the combinations of metal and the wiring which creates a silent barrier that repels rodents. This protective barrier preserves campers, antique cars, trucks, Rv's, tractors, combines and more. Also is great for metal storage sheds and pallet storage racks where wiring is less than plentiful.

Packaged in a box with attached hanger to be displayed on counter or hanging display.



FLOOR DISPLAY

Pest-A-Cator #2180 Holds 18 Units
Pest-A-Cator Too! #1180 Holds 24 Units

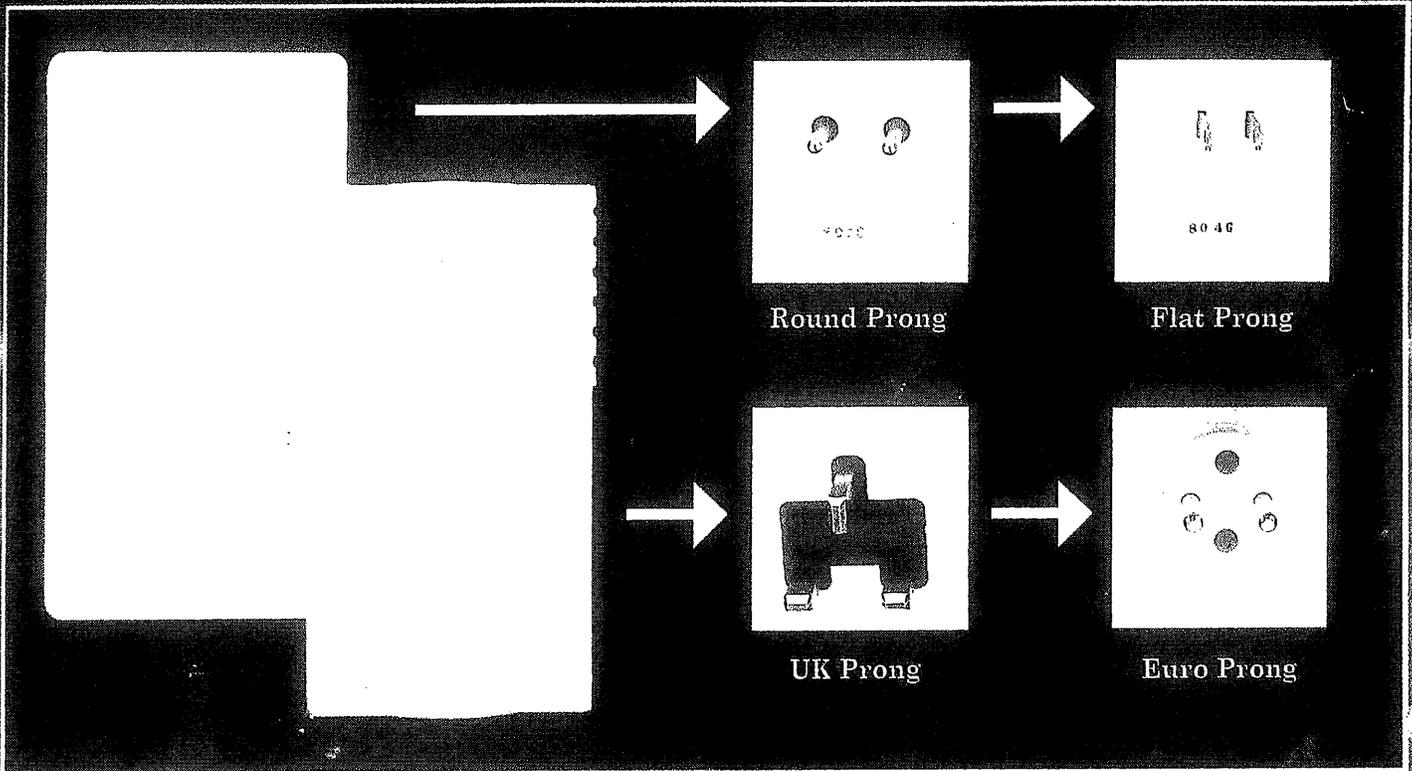


COUNTER DISPLAY

Pest-A-Cator #2140 Holds 6 Units
Pest-A-Cator Too! #1140 Holds 8 Units

TO ORDER CALL:
800-338-5028

PEST-A-CATOR[®] is also available in 220 volt upon request.



MONEY BACK GUARANTEE

Pest-A-Cator guarantees customer satisfaction. If not satisfied with results within 60 days, return the undamaged unit to place of purchase for a full refund. *Pest-A-Cator* is backed by a one year warranty on all parts and workmanship.

Pest-A-Cator Too!

#1140 - Set-up 15"L x 9"W x 14 1/4"H

Shipping Dimensions: 14" x 8 1/2" x 8 3/4"

Shipping Weight: 3 lbs.

#1180 - Set-up 14 1/2"L x 21 1/2"W x 54"H

Shipping Dimensions: 26 1/2" x 15" x 10 1/2"

Shipping Weight: 12 lbs.

DISPLAY DIMENSIONS

Pest-A-Cator

#2140 - Set-up 15"L x 9"W x 14 1/4"H

Shipping Dimensions: 14" x 8 1/2" x 8 3/4"

Shipping Weight: 4 lbs.

#2180 - Set-up 14 1/2"L x 21 1/2"W x 54"H

Shipping Dimensions: 26 1/2" x 15" x 10 1/2"

Shipping Weight: 13 lbs.

For Customer Service Call:

800-338-5028

Email - global@lyn.net



Manufactured by:

Global Instruments, Ltd.

Trenton, Missouri 64683



Another Quality
Product Made in USA

Phone: 660-359-4398

Fax: 660-359-5031

U.S.A. Patent No. 4,802,057
German Patent No. 8909186.8

EPA Est. No. 065887-CA-001
EPA Est. No. 066464-1A-001
EPA Est. No. 062471-1A-001

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Insect and Rodent Control Equipment
Listed 2904



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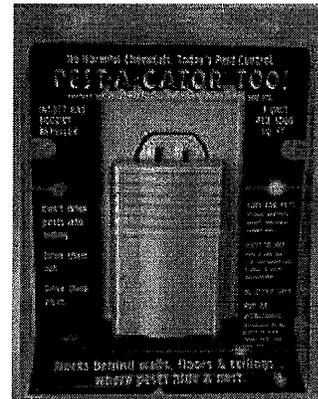
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PEST-A-CATOR TOO



PDF Brochure
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- Specially designed for smaller living quarters such as apartments, condominiums, mobile homes, etc...
- Works on mice, rats, and roaches.....Guaranteed or your money back!
- Works in areas up to 1000 square feet. Multiple units are needed for multiple stories. We recommend the original Pest-a-cator for areas larger than 1000 square feet.
- Fast working! Infested areas will be noticeably clean in 2 - 4 weeks.
- Direct plug-in feature is user friendly and convenient because it does not have to be plugged in plain view of infested areas.
- Safe for use around children and household pets (except rodent type pets).
- Helps in reducing monthly exterminator costs.
- Backed by a 60-day money back guarantee and a 1-year warranty on parts and workmanship.
- Another quality product manufactured in the USA.

Exhibit D



Global Instruments Ltd.

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Most Frequently Asked Questions Regarding Pulse Technology (Pest-A-Cator®)

- 1. How does it work?**
- 2. Where should I plug it in?**
- 3. How many are needed?**
- 4. Will it harm pets?**
- 5. Will it cause problems with computers or other electrical appliances?**
- 6. What is it guaranteed to work on?**
- 7. Can I use the unit outside?**
- 8. Will I ever see a pest after plugging in the Pest-A-Cator?**
- 9. What is the life expectancy of the unit and how can I tell if it is no longer working?**
- 10. What is the guarantee and warranty on Pest-A-Cator?**
- 11. Should I leave the unit plugged in all the time and how much electricity does the unit use?**
- 12. Will it affect a pacemaker?**
- 13. Will the unit work for bats or squirrels in the attic?**

Most Frequently Asked Questions Regarding Ultrasonic Technology (PestVacator®)

- 1. Does ultrasound penetrate walls, floors, ceilings or other solid objects?**
- 2. Will this product harm or interfere with the function of normal household products (i.e. Televisions, radios, computers or home security systems)?**
- 3. Will this product harm my pets?**
- 4. Will the product harm people who are pregnant or who have pacemakers?**
- 5. What does it cost to operate?**
- 6. Are people able to hear the sound put out by this product?**
- 7. Where is the best location to plug the unit in?**

Exhibit E

1. HOW DOES IT WORK?

Pest-A-Cator is NOT an ultrasonic product. It works with the electrical wiring in your home. The electrical wiring inside your home already has an existing field surrounding it. Pest-A-Cator, when plugged in, pulses this field. It doesn't really add to or take away from the field, just pulses it. Rats, mice, and cockroaches like to live and nest inside the walls. They feel this and don't like it and it drives them out. This means that if there is an infestation of rats, mice or roaches, the consumer WILL see more during the first four weeks or so, because it is driving them out of the walls. We recommend using traps, glue boards, etc. the first few weeks to help clean up the initial problem.

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2. WHERE SHOULD I PLUG IT IN?

We recommend plugging the unit into an outlet in a central location for a single level home of 2000 square feet or less (1000 square feet for Pest-A-Cator Too). If the home is single level and over 2000 square feet we recommend plugging a unit in at both ends of the home. For a multiple level home, please see Question #3. Since the unit is not an ultrasonic, it doesn't make any difference if the unit is plugged in behind furniture or curtains, etc. The unit only works where there is electrical wiring. For example, on a main floor of an average home, there is electrical wiring traveling throughout the walls of that level. The Pest-A-Cator would work fine. But, in an attic, or basement level, where the wiring may be concentrated in one area, say on the south end, and little or no wiring is on the north end, Pest-A-Cator would not be as effective on that level. Also, if a house is vacant or not always in use, the unit will not be as effective because the use of electrical appliances, lights, etc. is what creates the field that the unit works with. If no electricity is being used, the unit has nothing to work with.

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3. HOW MANY ARE NEEDED?

One unit covers up to 2,000 square feet (1000 square feet for Pest-A-Cator Too) in an average home. If the home has multiple levels, we recommend one per level and to plug them in at opposite ends of the home in a staggered effect (i.e.: two levels - one plugged in on the first floor at the north end, second unit plugged in on the second floor at the south end. Or 3 levels - first on first floor north end, second on second floor at south end, third unit on third floor at north end). If too many units are plugged into a small area (i.e.: one level less than 2000 square feet) they can interfere with each other and not be as effective.

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4. WILL IT HARM PETS?

We do not recommend using the unit if you have pets that are from the rodent family, such as hamsters, gerbils, rabbits etc. It will not effect birds, cats, dogs, and fish.

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5. WILL IT CAUSE PROBLEMS WITH COMPUTERS OR OTHER ELECTRICAL APPLIANCES?

No.

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6. WHAT IS IT GUARANTEED TO WORK ON?

Rats, Mice and Cockroaches ONLY! Consumer testimonials state that it works on ants, spiders, crickets, etc., but we do NOT guarantee it to work on these pests.

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7. CAN I USE THE UNIT OUTSIDE?

No. The unit is not recommended for use outside such as on patios, courtyards, etc. Also, it wouldn't work in such an area because electrical wiring does not surround it and the unit was not designed for outdoor use.

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8. WILL I EVER SEE A PEST AFTER PLUGGING IN THE PEST-A-CATOR?

Consumers may still see an occasional rat, mouse or cockroach that has wandered in, but they will not stay and take up residency in the home after a Pest-A-Cator is plugged in. If they can, they will leave the same way they came in.

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9. WHAT IS THE LIFE EXPECTANCY OF THE UNIT AND HOW CAN I TELL IF IT IS NO LONGER WORKING?

The AVERAGE life of a unit is 3 to 5 years. If the red light is no longer flashing (either completely out or a steady light) the unit is not working. Check light first. If light is flashing, but the consumer is having problems with rats, mice or cockroaches, try checking the unit for a vibration or "pull" using a metal screwdriver. Hold the tip of the screwdriver against the unit while the unit is plugged in. The unit cycles "on" for four minutes and "off" for two minutes. If no vibration or "pull" is felt when first testing the unit, wait a couple of minutes and try again as it may be in the "off" cycle. If, after waiting a couple of minutes and testing again there is still no vibration or "pull" the unit is no longer functioning.

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10. WHAT IS THE GUARANTEE AND WARRANTY ON PEST-A-CATOR?

There is a sixty-day money back guarantee and a one-year (from date of purchase) warranty on replacement of a defective unit.

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11. SHOULD I LEAVE THE UNIT PLUGGED IN ALL THE TIME AND HOW MUCH ELECTRICITY DOES THE UNIT USE?

It is best to leave the unit plugged in at all times, but it will not hurt to unplug it for very short periods of time. The unit uses about the same amount of electricity as a night light.

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12. WILL IT EFFECT A PACEMAKER?

Please use the same precautions that your doctor recommends you use with any other appliances. This device complies with part 15 of the FCC Rules. Operation is subject to the following conditions: (1) this device may not cause harmful interference, and, (2) this device must accept any interference received, including interference that may cause undesired operation.

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13. WILL THE UNIT WORK FOR BATS OR SQUIRRELS IN THE ATTIC?

While we have not tested for these particular pests, we have had customers offer this idea which they claimed worked for them.

How to manage squirrels in attics:

Wind or drape an outdoor extension cord in "S" turns throughout the entire attic. The extension cord should be no further than 5' from the previous row(cord) as this will ensure that the signal is completely covering 100% of the attic floor. The cord needs to be plugged into a live 110V wall outlet. Then plug the Pest-A-Cator device into the end of the extension cord. If using Pest-A-Cator Plus product, make sure the outlet that the device is plugged into is obstructive free, meaning clear with no beam or boxes, etc. in front of the unit, to allow the ultrasonic signal to work effectively. Any questions or confusion, please contact our Customer Service people at 1-800-338-5028.

How to manage bats in attic:

Same as managing squirrels in attics, but being the bats roost in the peaks of the attics, the extension cord needs to be raised to the ceiling level by using standard cup hooks (purchased from hardware or grocery stores). Make sure the cup hooks are mounted within 2' of the highest point in the attic. Now string the extension cords through the cup hooks and plug in as noted in "Managing squirrels in attics". Any questions or confusion, please contact our Customer Service people at 1-800-338-5028.

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1. DOES ULTRASOUND PENETRATE WALLS, FLOORS, CEILINGS OR OTHER OBJECTS?

No. Frequencies in the "ultrasound" range do not have the energy required to penetrate solid objects.

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2. WILL THIS PRODUCT HARM OR INTERFERE WITH THE FUNCTION OF NORMAL HOUSEHOLD PRODUCTS I.E., TELEVISION, RADIOS, COMPUTERS, OR HOME SECURITY SYSTEMS?

No.

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3. WILL THIS PRODUCT HARM MY PETS?

Dogs, cats, reptiles, and birds should not be effected by this product. The product can have adverse effects on rodent and spider type pets, such as, but not limited to, hamsters, gerbils, ferrets, and guinea pigs. We recommend that this product not be placed in the same room with these or any pet that begins to show signs of irritation when in proximity to the unit.

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4. WILL THE PRODUCT HARM PEOPLE WHO ARE PREGNANT OR HAVE PACEMAKERS?

No. Frequencies in the "ultrasound" range do not have the energy required to penetrate solid objects. This would include human tissue.

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5. WHAT DOES IT COST TO OPERATE?

Approximately 1 cent per day, depending on your local power rates.

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6. ARE PEOPLE ABLE TO HEAR THE SOUND PUT OUT BY THIS PRODUCT?

Ultrasound is in a frequency range just above human hearing, but some people with hearing sensitive to high frequency sounds may hear this unit as it works.

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7. WHERE IS THE BEST LOCATION TO PLUG THE UNIT IN?

Optimal position for the unit is into any unobstructed outlet where a pest problem exists.

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***"Imagine fingernails scraping a blackboard
24 hours a day!"***

PEST-A-CATOR®
PEST-A-CATOR® TOO

Well, that kind of irritation is the theory behind the *Pest-A-Cator* pest control device from Global Instruments. This is **not** one of those 'sonic' noise machines. The *Pest-A-Cator* uses the wiring in your home to turn the whole place into one huge, pest irritating machine which forces them to leave the premises.

Pest-A-Cator is the alternative to harmful or hazardous chemicals, pesticides and insecticides which can harm children, family pets*, friends, the environment and more. A single *Pest-A-Cator* unit will aid in ridding most standard 2,000 square foot areas of mice, rats and roaches within 2-4 weeks. The unique activity sends a pulsating signal throughout the wiring of homes, businesses and other structures. This silent pulse annoys insects and rodents, driving them out from behind walls, floors and ceilings where they hide and nest.

Just plug the *Pest-A-Cator* into any 110 outlet and let it go to work. One unit is all that is required for an average home up to 2,000 square feet. Additional units are needed for excess of 2,000 square feet or multiple story structures. The unique activity will not effect computers, telephones or other home appliances.

*Safe for all pets except hamsters, gerbiles, rabbits, and other rodent type pets.

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Exhibit F

1 **ON SCREEN: Exterminator**

2 **Pictures of monthly billing statements from**
3 **exterminator**

4 **MALE ANNOUNCER:** Or you can turn to the
5 exterminators and pay them to come back month after month
6 after month. And those were your alternatives until now.

7 Introducing a revolutionary unit that rids
8 homes of roaches, rats and mice without toxic chemicals,
9 harmful side effects, unsightly boxes or high monthly
10 fees.

11 **ON SCREEN: Pest-A-Cator product**

12 **MALE ANNOUNCER:** Introducing the Pest-A-Cator,
13 the safe and effective way to get rid of these pests once
14 and for all.

15 **ON SCREEN: 110 volt in U.S.**

16 **220 volt overseas**

17 **MALE ANNOUNCER:** This innovative technology
18 drives rodents and roaches out of your home and it's
19 completely safe for humans, as well as cats, dogs and
20 fish.

21 **ON SCREEN: (The PEST-A-CATOR will harm**
22 **hamsters, gerbils and other rodent pets.)**

23 **MALE ANNOUNCER:** Simply plug the Pest-A-Cator
24 into a standard outlet.

25 **ON SCREEN: Animation of Pest-A-Cator working**

1 in house

2 MALE ANNOUNCER: It starts to work immediately
3 by altering the normal field around your wiring, creating
4 an environment that aids in the control of mice, rats and
5 roaches where the problem exists, in the walls and
6 ceilings.

7 ON SCREEN: Animation of pests leaving home

8 MALE ANNOUNCER: Plus, it won't affect
9 computers or other electrical appliances while it drives
10 pests out of your home. And it's not ultrasonic.

11 ON SCREEN: PEST-A-CATOR uses 40 milliamps of
12 current -- less than 1 kilowatt to operate

13 MALE ANNOUNCER: It takes two to four weeks to
14 take care of normal pest and rodent problems.

15 ON SCREEN: Allow 2-4 weeks for infestations

16 MALE ANNOUNCER: Then your problem will be
17 gone --

18 ON SCREEN: Problem Gone!

19 MALE ANNOUNCER: -- and won't come back as long
20 as the unit is plugged in.

21 ON SCREEN: PEST-A-CATOR product

22 No Harmful Chemicals. Today's Pest Control.

23 Don't drive pests into hiding?

24 Drive them out...

25 Drive them away.

1 in house

2 MALE ANNOUNCER: It starts to work immediately
3 by altering the normal field around your wiring, creating
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For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

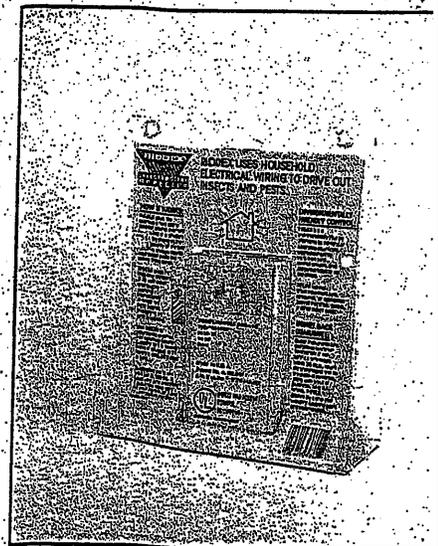
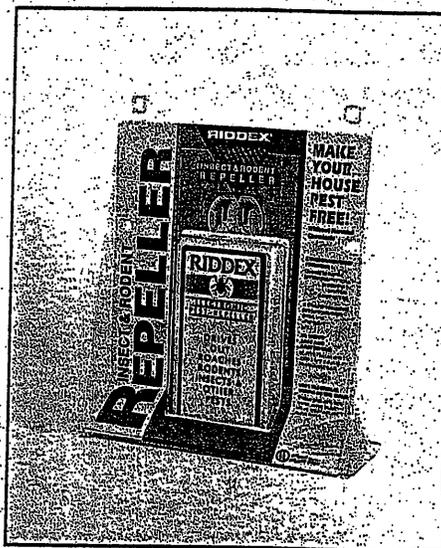
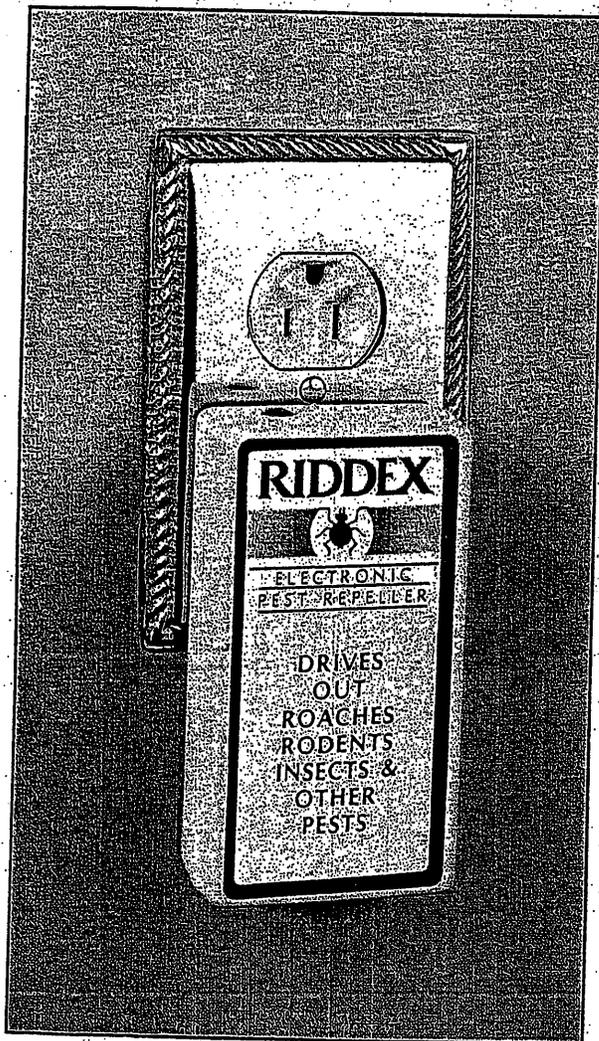
RIDDEX

INTRODUCING: **RIDDEX**®

“The Environmental Alternative For Safer Pest Control”

Want to reduce the use of hazardous chemicals (insecticides and pesticides) in your everyday life, around children, and food products? A new revolutionary invention has produced an innovative breakthrough in rodent and pest control; its name is “RIDDEX.” A recent U.S. patent has been issued for this new principle that safely and uniquely uses the wiring in a home, restaurant, office, or any structure with electrical wiring within the walls. Just plug in the “RIDDEX” to a standard 110 or 220 volt outlet and this new technology starts working by altering the normal field around your wiring, creating an environment that aids in the control of mice, rats, and roaches in the walls and ceiling where your problem exists.

House wiring turns your home into a giant pest repeller!



- Makes your home Pest-Free without harmful chemicals.
- Uses electrical wiring in the walls to drive pests away from homes, hotels, motels, offices, restaurants and mobile homes.
- Environmental Alternative.
- No need for pest control services.
- Will not harm household pets.
- U.L. and CSA listed safe and easy to use.
- Plugs into 110 or 220 volt outlet and Goes-To-Work Immediately.
- One unit takes care of an average home (2,000 sq. ft.)



Patent No. 4,802,057
German Patent No. 8909186.8

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Exhibit I

Made in U.S.A.

RIDDEX

What is a RIDDEX?

A RIDDEX is "The Environmental Alternative For Safer Pest Control"

Want to reduce the use of hazardous chemicals (insecticides and pesticides) in your everyday life, around children, and food products? A new revolutionary invention has produced an innovative breakthrough in rodent and pest control. A recent U.S. patent has been issued for this new principle that safely and uniquely uses the wiring in a home, restaurant, office, or any structure with electrical wiring within the walls.

How does it work?

Just plug in the RIDDEX to a standard 110 or 220 volt outlet and this new technology starts working by altering the normal field around your wiring, creating an environment that drives out mice, rats, and roaches from the walls and ceiling where your problem exists.

How many will I need?

One unit is all that is needed in most homes. (Approximately 2,000 sq. ft.)

How quickly will I see results?

Allow two to four weeks for satisfactory results. Glue boards may be used to help during initial clean-up period. After results have been obtained, do not unplug — the cost for continual use is minimal.

Money Back Guarantee

Global Instruments, Ltd., guarantees customer satisfaction. If not satisfied with results within 30 days, customers may return the undamaged unit to the place of purchase, along with proof of purchase, for a full refund. Global Instruments' products are backed by a one-year warranty covering parts and workmanship.

Instructions

Plugs into any 110 or 220 volt outlet (preferably in a central location in the home). The small red light will flash indicating the unit is working properly.

Won't harm household pets

Exceptions are hamsters, gerbils and other rodent pets.

- Fewer hazardous chemicals and baits which in turn lower children's and pets' exposure
- Laboratory (university) tested
- Cheaper than monthly pest control visits
- It is "NOT" ultrasonic (ultrasonics require one unit per room)
- Won't affect computers or appliances
- Reduces dangerous wire damage from rodent chewing
- Helps stop the spread of disease
- U.L., CSA listed
- Money back guarantee — one year warranty

QVC number - 1-800-345-15



Made in the U.S.A.



Insect and Rodent Control Equipment
Control No. 29U4



MANUFACTURED FOR:
Global Instruments, Ltd.
Worldwide Rodent and Pest Control
Trenton, Missouri 64683

Global Instruments Ltd.

PEST-A-CATOR^{plus}

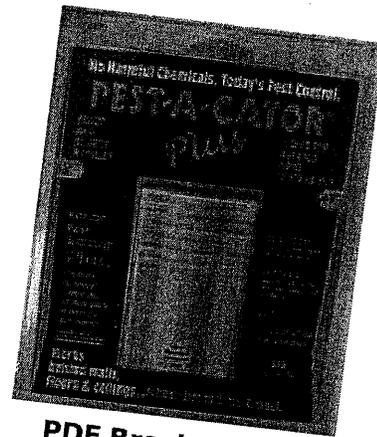
**Patented "Pulse" technology PLUS
Ultrasonic Technology creates the ultimate
power in electronic pest control!**

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- Pest-A-Cator Too Plus
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- Only 1 unit needed per Average home of 2000 sq. ft. (Larger single level or multistoried structures may need additional units).
- Direct plug-in feature is easy to use. Just plug the device into any 110V outlet.
- Safe around children & household pets (except rodent type pets).
- Completely maintenance-free! Not a chemical that washes away, not a trap that requires emptying dead or dying animals.
- Backed by a 60-day money back guarantee and a 1 year manufactures warranty!



**PDF Brochure
Advertising Photos**

2 TECHNOLOGIES IN 1!	
<p>"Pulse" Technology</p> <ul style="list-style-type: none"> • State of the art technology controls pest deep within the walls, ceilings and floors. • Guaranteed to aid with controlling on mice, rats and roaches. • Highly effective in areas up to 	<p>"Ultrasonic" Technology</p> <ul style="list-style-type: none"> • Older technology controls pest in problem areas. • Ultrasonic sound waves continue to bounce throughout the unobstructed room to aid with the control of pests on a continual basis.

2,000 sq. ft. and up to 1,000 sq. ft. with Pest-A-Cator Too Plus.

- Global Instruments patented technology.

- Aids in controlling rodents & insects (i.e. spiders, silverfish, etc.)

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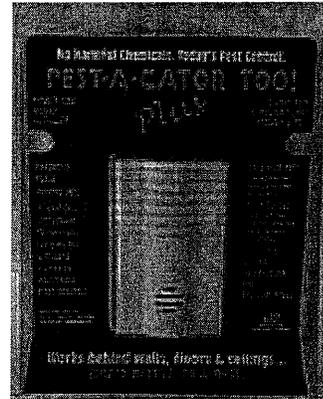
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PEST-A-CATOR TOO! *plus*

Patented "Pulse" technology PLUS Ultrasonic Technology creates the ultimate power in electronic pest control!

- Recommended for apartments, condominiums, multi-family and structures 1000 sq. ft. or less.
- Direct plug-in feature is easy to use. Just plug the device into any 110V outlet.
- Safe around children & household pets (except rodent type pets).
- Completely maintenance-free! Not a chemical that washes away, not a trap that requires emptying dead or dying animals.
- Backed by a 60-day money back guarantee and 1 year manufactures warranty!



PDF Brochure Advertising Photos

2 TECHNOLOGIES IN 1!	
<p>"Pulse" Technology</p> <ul style="list-style-type: none"> • State of the art technology controls pest deep within the walls, ceilings and floors. • Guaranteed to aid with controlling mice, rats and roaches. • Highly effective in areas up to 1,000 sq. ft. and up to 2000 Sq. Ft. with Pest-A-Cator Plus. 	<p>"Ultrasonic" Technology</p> <ul style="list-style-type: none"> • Older technology controls pest in problem areas. • Ultrasonic sound waves continue to bounce throughout the unobstructed room to aid with control of pests on a continual basis. • Aids in controlling rodents & insects (i.e. spiders, silverfish

Exhibit K



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PestVacator[®]
Electronic Insect & Rodent Repeller

- Ultrasonic technology
- Aids in ridding the protected area of unwanted pests - up to 800 Sq. Ft. of protection!
- Cost only pennies a day to operate.
- Silently protects areas 24-hours a day, 365 days a year.
- Direct plug-in feature is easy to use. Just plug the device into any 110V outlet.
- Safe for household pets (except rodent and spider type pets).
- No toxic chemicals, posions or traps needed.
- Backed by a one-year limited warranty!



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Exhibit L

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondents of all the jurisdictional facts set forth in the complaint, a statement that the signing of said Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondents had violated the Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34(f) of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following Order:

1. Respondent Global Instruments Ltd. is an Iowa corporation with its principal office or place of business at 819 Industrial Drive, Trenton, Missouri 64683.
2. Respondent Charles Patterson is President of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the

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corporation. His principal office or place of business is the same as that of Global Instruments Ltd.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. "Pest-control product" shall mean any Pest-A-Cator, Pest-A-Cator Too!, Pest-A-Cator Plus, Pest-A-Cator Too! Plus, Riddex, Riddex Jr., PestVacator 800, or PestVacator 1500, or any other product designed, advertised, or intended to repel, control, drive away, or eliminate any insect or animal pest, including but not limited to, mice, rats, and cockroaches.
3. Unless otherwise specified, "respondents" shall mean Global Instruments Ltd., a corporation, its successors and assigns and its officers; Charles Patterson, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.
4. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

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I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any pest-control product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such pest-control product:

- A. repels, controls, drives away, or eliminates, temporarily or indefinitely, mice, rats, cockroaches, or any other insects or animal pests,
- B. repels, controls, drives away, or eliminates any mice, rats, cockroaches, or any other insects or animal pests in a desired area or an area of a certain size,
- C. is an effective alternative to or eliminates the need for chemicals, pesticides, insecticides, exterminators, or any other pest control product or service, or
- D. will alter the electromagnetic field, send a pulsating signal, or otherwise work inside the walls or through the wiring of homes, offices, schools, restaurants, hospitals, or other buildings in a manner that effectively repels, controls, or eliminates mice, rats, cockroaches or any other insects or animal pests, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product,

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in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent Global Instruments Ltd., and its successors and assigns, and respondent Charles Patterson shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IV.

IT IS FURTHER ORDERED that respondent Global Instruments Ltd., and its successors and assigns, and respondent Charles Patterson shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and

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shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondents shall retain the signed, dated statements acknowledging receipt of the order for a period of five (5) years and upon request make them available to the Federal Trade Commission for inspection and copying.

V.

IT IS FURTHER ORDERED that respondent Global Instruments Ltd., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VI.

IT IS FURTHER ORDERED that respondent Charles Patterson, for a period of three (3) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment with Global Instruments Ltd., or of his affiliation with any new business or employment

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involving the marketing of any consumer product. The notice shall include the respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that respondent Global Instruments Ltd., and its successors and assigns, and respondent Charles Patterson shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

VIII.

This order will terminate on August 22, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

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Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Harbour not participating.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Global Instruments Ltd. and Charles Patterson, individually and as an officer of the corporation.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns practices related to the advertising, offering for sale, sale, and distribution of various electromagnetic, ultrasonic, and combination electromagnetic and ultrasonic pest control devices. The Commission's proposed complaint alleges that proposed respondents violated section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by making numerous representations about Global's pest control products for which they lacked a reasonable basis. Specifically, the complaint alleges that the following representations were unsubstantiated:

- Global's **electromagnetic** pest control products repel, drive away, or eliminate mice, rats, and cockroaches from homes and other buildings in two to four weeks and drive them away by sending a pulsating signal throughout or altering the field around the electrical wiring inside homes and other buildings; they act as an effective alternative to or eliminate the need for chemicals, pesticides, insecticides, exterminators, and pest control services;
- Global's **combination electromagnetic/ultrasonic** pest control devices effectively repel, control or eliminate mice, rats, cockroaches, rodents, insects, spiders, silverfish, and bats from homes and other buildings and upset nesting sites of mice, rats, and cockroaches within walls, ceilings, and floors

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by using the products' pulse or electromagnetic technology through the household wiring;

- Global's **ultrasonic** pest control devices effectively repel, drive away, or eliminate mice, rats, bats, crickets, spiders and other insects from homes and eliminate the need for toxic chemicals, poisons or traps; and
- Global's pest control products are effective within a space of a given size (for example, 1000 sq. ft. or 2000 sq. ft.).

The proposed consent order contains provisions designed to prevent proposed respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits the following representations unless respondents possess competent and reliable scientific evidence that substantiates the representations:

- that any pest control product repels, controls, or eliminates, temporarily or indefinitely, mice, rats, cockroaches, or any other insects or animal pests and that it does so in an area of a certain size;
- that any pest control product is an effective alternative to or eliminates the need for chemicals, pesticides, insecticides, exterminators, or any other pest control product or service; and
- that any pest control product will alter the electromagnetic field, send a pulsating signal, or otherwise work inside the walls or through the wiring of homes or other buildings in a manner that effectively repels, controls, drives away, or eliminates mice, rats, cockroaches, or any other insects or animal pests.

Part II of the proposed order requires respondents to possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, for claims about the benefit, performance, or efficacy of any product.

Part III of the proposed order requires the respondents to maintain certain records for five years after the last date of dissemination of any representation covered by the order. These

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records include: (1) all advertisements and promotional materials containing the representation; (2) all materials relied upon in disseminating the representation; and (3) all evidence in respondents' possession or control that contradicts, qualifies, or calls into question the representation or the basis for it.

Part IV of the proposed order requires distribution of the order to current and future principals, officers, directors, and managers, and to current and future employees, agents, and representatives having responsibilities with respect to the subject matter of the order.

Part V of the proposed order requires that the Commission be notified of any change in the corporation that might affect compliance obligations under the order. Part VI of the proposed order requires that for a period of three years, respondent Charles Patterson will notify the Commission of the discontinuance of his current business or employment or of his affiliation with any new business or employment involving the marketing of any consumer product.

Part VII of the proposed order requires the respondents to file a compliance report with the Commission.

Part VIII of the proposed order states that, absent certain circumstances, the order will terminate twenty (20) years from the date it is issued.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

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IN THE MATTER OF

THE MAINE HEALTH ALLIANCE, ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4095; File No. 0210017*
Complaint, August 27, 2003--Decision, August 27, 2003

This consent order, among other things, prohibits Respondent The Maine Health Alliance – a nonprofit corporation consisting of more than 325 physicians and 11 hospitals in northeastern Maine – and its Executive Director, Respondent William R. Diggins, from entering into or facilitating any agreement between or among any physicians (1) to negotiate with payors on any physician’s behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through the Alliance. The order also prohibits the respondents from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in – or from encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order. The order also prohibits the respondents from participating in, or creating, future unlawful agreements for hospital services. In addition, the order requires the Alliance to notify the Commission at least 60 days prior to negotiating or entering into certain agreements with payors related to qualified risk sharing or clinically intergrated joint arrangements– or discussing price or related terms among the participants of such arrangements – and, at any payor’s request and without penalty, to terminate its current contracts with respect to providing physician services. The order also requires the alliance to terminate all current contracts not otherwise terminated no later than one year from the date the order becomes final.

Participants

For the Commission: *Robert S. Canterman, Christi Braun, Mary Connelly-Draper, David R. Pender, Markus M. Meier, Jeffrey W. Brennan, Anne R. Schenof, Daniel P. Ducore, and Louis Silvia .*

For the Respondents: *Wayne A. Mack, Duane Morris, LLP, and John J. Miles, Ober, Kaler, Grimes & Shriver.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the Maine Health Alliance (the “Alliance”) and William R. Diggins (the “Respondents”) have violated and are violating Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

The Nature of the Case

1. Acting through the Alliance, the vast majority of hospitals and physicians located in a five-county area of northeastern Maine have agreed to limit competition among themselves by collectively negotiating contracts – including price terms – with employers, health insurers, and others seeking to provide health-care coverage to the people of northeastern Maine (“payors”). Further, these eleven hospitals and more than 325 physicians have refused to contract individually with those unwilling to meet the Alliance’s collective terms. These price-fixing agreements and concerted refusals to deal among otherwise competing hospitals and among otherwise competing physicians, in turn, have kept the price of health care in northeastern Maine above the level that would have prevailed absent the Alliance’s illegal conduct. The Alliance has not undertaken any efficiency-enhancing integration sufficient to justify its challenged conduct.

The Respondents

2. The Alliance is a taxable, nonprofit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Maine, and its principal address is 12 Stillwater Avenue, Suite C, Bangor, Maine 04401. The Alliance was formed in 1995, and its membership currently consists of over 325 physicians and

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eleven hospitals located throughout a five-county area in northeastern Maine.

3. William R. Diggins is the Alliance's Executive Director, and he has served in this capacity since its inception. As Executive Director, Mr. Diggins manages the Alliance's day-to-day operations, and he is one of the organization's principal contract negotiators with payors. Mr. Diggins' principal address is 12 Stillwater Avenue, Suite C, Bangor, Maine 04401.

Jurisdiction and Interstate Commerce

4. The Alliance's eleven hospital members are: Calais Regional Hospital, Cary Medical Center, Down East Community Hospital, Houlton Regional Hospital, Maine Coast Memorial Hospital, Mayo Regional Hospital, Millinocket Regional Hospital, Mount Desert Island Hospital, Northern Maine Medical Center, Penobscot Valley Hospital, and St. Joseph Hospital. Each of these hospitals is a tax-exempt organization. The Alliance is not a tax-exempt entity.

5. The Alliance's approximately 325 physician members include both primary care and specialist physicians. A substantial majority of these physicians practice in independent solo or small group practices on a for-profit basis. Some physician members are salaried employees of an Alliance hospital.

6. At all times relevant to this complaint, a substantial majority of the Alliance's physician members have been engaged in the business of providing medical services for a fee. Except to the extent that competition has been restrained as alleged herein, Alliance physicians have been, and are now, in competition with other Alliance physicians for the provision of physician services.

7. At all times relevant to this complaint, the Alliance's hospitals have been engaged in the business of providing hospital services for a fee. Except to the extent that competition has been restrained as alleged herein, Alliance hospitals have been, and are

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now, in competition with other Alliance hospitals for the provision of hospital services.

8. The Alliance's bylaws provide that physician members hold 11 of the 22 seats on the Alliance's Board of Directors ("Board"). The physician members at each of the 11 Alliance hospitals elect a representative to the Board. In addition, each Alliance hospital appoints a hospital representative to serve on the Alliance Board. The Board is the Alliance's chief policy-making body.

9. The Alliance is organized in substantial part, and is engaged in substantial activities, for the pecuniary benefit of its members, and is therefore a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

10. The Respondents' general business practices and conduct, including the acts and practices alleged herein, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

11. According to the Alliance's records, as of 2002, the contracts that the Respondents and others have negotiated with payors and entered into on behalf of the Alliance's physicians and hospital members represent "in excess of 100 million dollars in commercial revenue."

Overview of the Market and Competition

12. The Alliance and its physician and hospital members do business in Aroostook, Hancock, Penobscot, Piscataquis, and Washington Counties in northeastern Maine (the "Northeastern Maine Counties").

13. Physicians often contract with payors to establish the terms and conditions, including price and other competitively significant terms, under which they will provide services to subscribers of health plans.

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14. Hospitals, likewise, often enter into contracts with payors to establish the terms and conditions, including price and other competitively significant terms, under which they will provide services to subscribers of health plans.

15. Physicians and hospitals entering into payor contracts often agree to discount or lower their prices in exchange for access to additional patients made available by the payors' relationship with their subscribers. These contracts may reduce payors' costs and enable payors to lower the price of health insurance, and reduce out-of-pocket medical care expenditures by subscribers to the payors' health insurance plans.

16. Absent agreements among physicians or hospitals on prices and other contract terms on which they will provide services to subscribers of health plans, competing physicians and competing hospitals decide individually whether to enter into contracts with payors, and at what prices they will accept payment for services rendered pursuant to such contracts.

17. The Medicare Resource Based Relative Value Scale ("RBRVS") is a system used by the Centers for Medicare and Medicaid Services ("CMS") to determine the amount to pay physicians for the services they render to Medicare patients. Under RBRVS, the price for physician services is determined by multiplying a dollar conversion factor, set by CMS, by the Relative Value Unit ("RVU") assigned by CMS to each physician service (*e.g.*, under RBRVS, a Medicare conversion factor of \$35 x 2.34 RVU for a physician service = an \$82 fee). Payors in many areas of the country make contract offers to individual physicians or groups at a price level specified as some percentage of the RBRVS fee for a particular year (*e.g.*, "110% of 2003 RBRVS"). In the Northeastern Maine Counties, payors negotiate the conversion factor, rather than a percentage of the RBRVS fee, with physicians. For example, if a Maine payor offers a conversion factor of \$42, rather than the Medicare conversion factor of \$35, and the RVU that CMS assigns for a particular

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physician service is 2.34, then the physician's price for that service to the payor would be $\$42 \times 2.34$, or $\$98.28$.

18. The Maine Bureau of Insurance has promulgated access to care regulations requiring health maintenance organizations ("HMOs") to make physician and hospital services available within certain travel times and distances from the residences of the HMO's subscribers. To comply with these regulations, an HMO doing business in the Northeastern Maine Counties must include in its provider network a large number of primary care and specialist physicians and hospitals that provide services in the Northeastern Maine Counties.

19. To be competitively marketable in the Northeastern Maine Counties, a payor's health plan must include in its provider network a large number of primary care and specialist physicians and hospitals in the Northeastern Maine Counties.

20. The substantial majority of the primary care and specialist physicians who practice in the Northeastern Maine Counties are members of the Alliance, and more than 85% of the physicians on staff at the Alliance's hospitals are members of the Alliance. Eleven of the sixteen hospitals in the Northeastern Maine Counties are members of the Alliance.

**The Alliance Is a Joint Contracting Organization,
and Acts as an Exclusive Contracting Agent, for Its Members**

21. According to its business records, the Alliance was formed primarily to serve as a "joint contracting organization" for its physician and hospital members, and to negotiate payor contracts that contain "higher compensation" and other more "advantageous" contract terms than its physician and hospital members could obtain by dealing individually with payors. Moreover, as set forth in the Alliance's 1998 Strategic Plan, its "mission" is to provide Alliance members with "increased market strength through joint contracting."

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22. The Alliance Board, in conjunction with its Contracts Committee, has compiled written “Contracting Guidelines and Parameters” setting forth price-related and other competitively significant terms that the Alliance requires when contracting with payors on its members’ behalf.

23. As part of the process of joining the Alliance, physicians and hospitals sign an agreement designating the Alliance as their negotiating agent to contract with payors, and authorizing the Alliance to enter into, on their behalf, payor contracts that meet the organization’s “Contracting Guidelines and Parameters.”

24. The Board has authorized Mr. Diggins to serve as one of the Alliance’s principal negotiating agents with payors. Mr. Diggins reports the details of Alliance negotiations with payors, including the status of price negotiations and the specific price levels that are discussed, to the Alliance’s Contracts Committee and the Board.

25. The Board relies on Mr. Diggins’s recommendations in deciding whether to accept or reject a payor contract on behalf of the Alliance’s physician and hospital members.

26. In correspondence with Alliance physicians, Mr. Diggins has touted “the favorable compensation which the Alliance has obtained for its physician members.” Alliance representatives, including Mr. Diggins, demanded and received payor contracts containing higher conversion factors used to determine prices for physician services than physicians were able to obtain through direct, unilateral negotiations with payors. As a result of the higher conversion factors that the Alliance demanded, the Alliance physicians received higher compensation for their services.

27. Alliance hospitals determine their own respective price lists. The Alliance, representing the hospitals collectively, fixes the maximum percentage discount allowable from member hospital price lists. In correspondence with Alliance hospitals,

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Mr. Diggins asserted that “Alliance contracting has frequently afforded its members better compensation than its individual hospitals could have obtained unilaterally,” by demanding and receiving smaller discounts off the hospital’s charges and refusing payor requests to negotiate the hospital list prices underlying the discounts.

28. The Alliance and Mr. Diggins, on the Alliance members’ collective behalf, also have negotiated competitively significant contract terms in addition to price, resulting in higher compensation than the physicians and hospitals could have obtained without the Alliance’s collective bargaining power (*e.g.*, large monetary penalties for failure to pay in a timely manner, and restrictions on how payors utilize software programs to review physicians’ claims for payment).

29. Although the Alliance’s rules and bylaws state that its physician and hospital members are permitted to participate in other provider networks and to negotiate with payors individually, the Alliance and Mr. Diggins have repeatedly convinced Alliance members to contract exclusively through the organization. They have done so by, among other things:

- a. urging Alliance physicians, when contacted individually by payors, to “refer them to the Alliance” to enhance the group’s collective power;
- b. facilitating efforts by Alliance physicians to “roll their [pre-existing individual payor] contracts through the Alliance” when they came up for renewal, to benefit from the more lucrative terms that the Alliance demands from payors;
- c. discouraging Alliance physicians from contracting with other provider networks, and encouraging those who already are members of other networks to “reconsider [their] participation” in those networks, to maintain the Alliance’s collective power; and

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- d. warning Alliance hospitals that contracting outside the Alliance will “‘gut’ the organization” and “diminish” its purpose and effectiveness.

30. By agreeing with each other to negotiate concertedly through the Alliance, the Alliance’s physician members and hospital members have obtained higher compensation and other more favorable contract terms from payors than they would have by negotiating with payors individually.

Aetna, Inc.

31. In September 1996, the Alliance entered into a contract with NYLCare Health Plans of Maine, Inc. (“NYLCare”), a payor doing business in the Northeastern Maine Counties. In 1998, Aetna, Inc. (“Aetna”), acquired NYLCare, and assumed all of NYLCare’s contracts with physicians and hospitals in the Northeastern Maine Counties, including NYLCare’s contract with the Alliance.

32. Through contract negotiations with NYLCare in 1996, the Alliance, on behalf of its physician members, demanded and received a \$65 conversion factor, which is equivalent to approximately 175% of 1996 RBRVS, for services performed for non-HMO subscribers. For NYLCare’s HMO subscribers, the Alliance successfully negotiated a \$52 conversion factor, which is equivalent to approximately 140% of 1996 RBRVS. At that time, NYLCare contracted with non-Alliance physicians for services rendered to all NYLCare subscribers (HMO and non-HMO) in Maine at conversion factors ranging from \$48 to \$50, which is equivalent to approximately 130% to 135% of 1996 RBRVS. The prices obtained by the Alliance for its physician members were substantially higher than the physicians could have obtained by negotiating individually with NYLCare.

33. Since Aetna’s acquisition of NYLCare in 1998, Aetna and non-Alliance physicians have renegotiated their contracts, resulting in savings for Aetna subscribers. Aetna currently utilizes

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conversion factors ranging from \$44 to \$48, which is approximately equivalent to 120% to 130% of 2003 RBRVS, for services rendered by non-Alliance physicians to its subscribers in Maine. Aetna has made repeated attempts to renegotiate the rates that it pays to the Alliance's physician members, but the Alliance, on the collective behalf of its physician members, has refused to reduce the \$65 and \$52 conversion factors for physician services agreed to in 1996. As a result, Aetna pays Alliance physicians prices that are approximately 40% to 50% higher for non-HMO subscribers, and 10% to 20% higher for HMO subscribers, than Aetna pays to non-Alliance physicians for comparable services.

34. The Alliance's contract with Aetna was set to expire August 31, 1999. In a letter dated March 8, 1999, Aetna approached Alliance physicians directly to negotiate new contracts with individual physicians, to ensure that there would be no interruption of service to its subscribers if Aetna and the Alliance failed to reach an agreement for renewal prior to the termination of the contract.

35. In response to Aetna's attempt to negotiate with Alliance physicians unilaterally, Mr. Diggins told Alliance physicians in a March 18, 1999 memorandum that "[t]he Alliance has strenuously objected" to Aetna about its "bold effort at recruiting physicians around the Alliance." In addition, Mr. Diggins warned the physicians that Aetna's contract offer to the physicians would reduce physician compensation to a conversion factor of \$44, which Mr. Diggins characterized as a "significant reduction in compensation" and one to which Aetna realized "the Alliance is unlikely to agree." The \$44 conversion factor, which is equivalent to approximately 127% of 1999 RBRVS, was Aetna's arrangement with non-Alliance physicians in 1999.

36. On March 17, 1999, the Alliance's lawyer and business agent sent a letter to Aetna, demanding that Aetna: (a) retract its offers for direct contracts with Alliance physicians; (b) notify the physicians that the Alliance's contract with Aetna governs the relationship between the physicians and Aetna; and (3) "return,

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marked void, to the physician any contract executed by the physician” in response to Aetna’s offer.

37. The Alliance physicians collectively refused to deal with Aetna, other than as a group through the Alliance, and forced Aetna to renew its contract with the Alliance at the \$65 and \$52 conversion factor rates. Without Alliance physician members in its network, Aetna would have been unable to maintain a competitively marketable health plan in the Northeastern Maine Counties and comply with the Maine Bureau of Insurance access to care regulations.

38. The Alliance’s hospital members also negotiated collectively through the Alliance with NYLCare/Aetna for a contract. In 1996, the Alliance, on behalf of its hospital members, negotiated a 5.5% discount from billed charges for services rendered to NYLCare non-HMO subscribers, and an 11% discount from billed charges for services rendered to NYLCare HMO subscribers. Both of these discounts were approximately 33% smaller than the discounts that NYLCare contracted for, on average, with non-Alliance hospitals for the same health plan products. Since it acquired NYLCare, Aetna has attempted to negotiate with the Alliance for new hospital prices. The Alliance refused to accept lower prices and has continuously demanded higher prices.

39. In 1999, the Alliance demanded that Aetna agree to a 6% discount from billed charges for all services provided by Alliance hospitals to Aetna’s HMO and non-HMO subscribers. In response, Aetna proposed different rates for different Alliance hospitals, which provide varying services and levels of care. The Alliance refused to agree to anything other than a single discount rate for all of its member hospitals. Aetna counter-offered a 15% discount, which equaled Aetna’s statewide average discount for Maine hospitals. The Alliance also rejected this offer, continuing to insist upon a 6% discount. Due to a stalemate over compensation, the Alliance continues to provide services to Aetna subscribers under the terms of the 1996 Alliance-NYLCare

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contract, which pays Alliance hospitals substantially higher prices than Aetna pays to non-Alliance hospitals. Without the Alliance hospitals in its network, Aetna would have been unable to maintain a competitively marketable health plan in the Northeastern Maine Counties and comply with Maine Bureau of Insurance access to care regulations.

Cigna HealthCare of Maine, Inc.

40. Cigna HealthCare of Maine, Inc. (“Cigna”), is a payor doing business in the Northeastern Maine Counties that contracts with the Alliance for physician and hospital services. In May, 1998, on the collective behalf of Alliance hospital members, the Alliance told Cigna that it must reduce the discount off hospital charges that Cigna received under its existing agreement with the Alliance. In December, 1998, having no reasonable alternative but to meet the Alliance’s demand, Cigna reduced, by almost 50 percent, the discount that it received off Alliance hospital charges. This resulted in substantially higher prices paid to those hospitals.

41. In August, 2001, four months prior to the expiration date of its contract with the Alliance, Cigna directly approached the Alliance’s physician and hospital members to negotiate individual contracts containing price terms to which the physicians and hospitals would agree unilaterally, not collectively through the Alliance.

42. Upon reviewing the terms of the contract Cigna was offering Alliance members individually, Mr. Diggins advised Alliance members that the contract’s prices and price-related terms were unacceptable, and that they should not accept Cigna’s offer.

43. Mr. Diggins also provided the Alliance’s physician and hospital members with a model letter for them to use to notify Cigna that they refused to negotiate individually, and that the Alliance would negotiate on their behalf. Shortly thereafter, the physician and hospital members sent almost identical letters to

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Cigna, stating that they would not enter into direct contracts with Cigna and that Cigna should negotiate with the Alliance. As the termination date for the Alliance's Cigna contract approached, Alliance physician members started to notify Cigna that they would no longer provide services to Cigna health plan enrollees.

44. The Alliance and Mr. Diggins demanded, on behalf of Alliance physician and hospital members collectively, that Cigna continue contracting through the Alliance, and that Cigna agree to the Alliance's demands concerning a number of competitively significant price terms. These demands included continuing the limits on discounts off hospital charges, rejecting Cigna's request to negotiate the hospital list prices underlying the discounts, and rejecting Cigna's request to renegotiate physician prices.

45. Cigna was forced to continue contracting with the Alliance on the Alliance's collectively demanded terms because, without a majority of Alliance physician and hospital members in its network, Cigna would have been unable to maintain a competitively marketable health plan in the Northeastern Maine Counties and comply with the Maine Bureau of Insurance access to care regulations.

Anthem Health Plans of Maine, Inc.

46. The Alliance and Blue Cross and Blue Shield of Maine ("Blue Cross"), a payor then doing business in the Northeastern Maine Counties, entered into a contract in September, 1997, for the provision of services by the Alliance's hospital members. The agreement provided that Alliance hospital members be paid their billed charges, minus a 6% discount, during the remaining months of 1997, and billed charges minus a 7% discount, for the calendar years 1998 and 1999. Blue Cross had sought lower prices through deeper discounts, but the Alliance hospitals collectively refused to alter their terms. The Alliance's business records show that, by fixing the discount rate, the eleven Alliance hospitals increased their combined annual revenues by approximately \$700,000.

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47. On June 5, 2000, Anthem Health Plans of Maine, Inc. (“Anthem”), purchased Blue Cross and assumed the Alliance contract. Over the course of negotiations lasting nearly two years, the Alliance insisted that Anthem replace its individual physician contracts with an Alliance contract, and that Anthem not reduce its compensation to Alliance member physicians under the existing individual contracts.

48. In mid-2002, Mr. Diggins told Anthem that the Alliance’s physicians would terminate their individual contracts with Anthem, unless Anthem agreed to contract through the Alliance for the physicians’ services, at prices agreeable to them collectively. Concerned about losing the Alliance providers from its network, Anthem agreed to include the physicians in its contract with the Alliance, and engaged in several more months of price negotiations. In the midst of the investigation of the Alliance by the Federal Trade Commission and the State of Maine’s Office of Attorney General, the Alliance notified Anthem that it could not go forward with the new contract, which would have included all Alliance physician and hospital members, and agreed to an additional one year extension of the 1997 hospital-only contract.

Harvard Pilgrim Health Care, Inc.

49. In early 1999, Harvard Pilgrim Health Care, Inc. (“Harvard Pilgrim”), approached the Alliance about contracting for physician and hospital services, which would allow Harvard Pilgrim to offer an HMO product in the Northeastern Maine Counties.

50. During contract negotiations with Harvard Pilgrim, the Alliance demanded high compensation for its members. The Alliance told Harvard Pilgrim that its hospital members “have been willing to accept discounts on charges ranging up to 7%,” and “[p]hysician compensation agreed to has ranged from \$47 [conversion factor] to \$51 [conversion factor].” The Alliance’s rates were substantially higher than Harvard Pilgrim’s standard compensation terms. Nevertheless, Harvard Pilgrim offered the

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Alliance a 7% discount for its hospital members and a \$47 conversion factor for its physicians, which is equivalent to approximately 135% of 1999 RBRVS. The Alliance rejected the offer and countered with a 4% discount off of charges for hospital services and a conversion factor of \$49.95 for physician services, which is equivalent to approximately 144% of 1999 RBRVS.

51. The Alliance's repeated demands for higher compensation resulted in Harvard Pilgrim abandoning its contracting efforts with the Alliance. Harvard Pilgrim approached individual Alliance physicians and hospitals for contracts directly with Harvard Pilgrim, but was unable to sign enough physicians and hospitals to create a network. As a result, Harvard Pilgrim does not offer an HMO product in the Northeastern Maine Counties.

Fraser Paper, Inc.

52. Fraser Paper, Inc. ("Fraser Paper"), a large employer in the Northeastern Maine Counties, covers approximately 2,300 individuals under a self-insured health plan. In 1997, Fraser Paper attempted to create its own provider network by entering into individual contracts with the Alliance physician and hospital members located near Fraser Paper employees. The physicians and hospitals refused to deal directly with Fraser Paper, and told Fraser Paper that the Alliance would negotiate collectively on their behalf. Confronted with the physicians' and hospitals' refusals to deal individually, Fraser Paper entered into a contract with the Alliance in 1998.

53. Fraser Paper sought to include only two Alliance hospitals in its network, but, because of the Alliance's restrictive policy, was compelled to include all Alliance hospitals as a condition of dealing with the Alliance. This prevented Fraser Paper from selecting particular hospitals with which to negotiate for inclusion in its network. Absent the Alliance's demand, Fraser Paper could have offered select hospitals access to Fraser Paper's employees in exchange for a significant reduction in the hospitals' prices.

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54. Since 1998, Alliance hospitals have raised their charges for hospital services by as much as 15%. Fraser Paper made several attempts to negotiate larger discounts off the hospitals' charges to offset these increases, but the Alliance refused. The Alliance also rejected Fraser Paper's offers to negotiate the hospitals' charges underlying the discounts.

55. Fraser Paper attempted to contract directly with Alliance physician and hospital members on several occasions from 1998 to 2001, and to address its concerns over high health care costs. In each instance, the Alliance physician and hospital members refused to negotiate individual contracts, and directed Fraser Paper to contract with the Alliance.

Other Payors

56. Respondents have informed other payors that the Alliance represented the collective interest of its physician and hospital members, and that the Alliance would negotiate and sign contracts on behalf of all its physician and hospital members. Respondents also informed these payors of the specific price and price related terms that the Alliance demanded as a condition for signing a contract. To exert pressure on and coerce these payors to agree to the Alliance terms, Alliance physician and hospital members informed such payors that they would not negotiate individually, and told the payors to contract for the Alliance members' services only through the Alliance. As a result of the collective conduct, the Alliance has successfully obtained contracts on behalf of its physicians and hospitals with these payors on terms demanded by the Alliance.

The Alliance's Conduct Has Restrained Trade

57. The Alliance, acting as a combination of its members, combining or conspiring with its members, and acting through Mr. Diggins and others, has restrained competition by, among other things:

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- a. facilitating, negotiating, entering into, and implementing agreements among Alliance physicians on price and other competitively significant terms;
- b. refusing to deal with payors except on collectively agreed-upon terms; and
- c. negotiating uniform prices and other competitively significant terms in payor contracts for Alliance physicians.

58. The Alliance, acting as a combination of its members, combining or conspiring with its members, and acting through Mr. Diggins and others, has restrained competition by, among other things:

- a. facilitating, negotiating, entering into, and implementing agreements among Alliance hospitals on price and other competitively significant terms;
- b. refusing to deal with payors except on collectively agreed-upon terms; and
- c. negotiating uniform discounts from hospital charges and other competitively significant terms in payor contracts for Alliance hospitals.

**The Alliance Has Not Created Significant Efficiencies
Justifying Its Conduct**

59. In collectively negotiating and entering into contracts with payors, the Alliance and its physician and hospital members have failed to engage in any significant form of financial risk sharing or clinical integration. Respondents' negotiation of prices and other competitively significant contract terms on behalf of Alliance members has not been, and is not, reasonably related to any efficiency-enhancing integration among the Alliance's physician and hospital members.

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The Alliance's Conduct Has Had Anticompetitive Effects

60. Respondents' actions described in Paragraphs 11 through 58 of this Complaint have had, or tend to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician and hospital services in the Northeastern Maine Counties in the following ways, among others:

- a. price and other forms of competition among Alliance physicians were unreasonably restrained;
- b. price and other forms of competition among Alliance hospitals were unreasonably restrained;
- c. prices for physician services were increased;
- d. prices for hospital services were increased;
- e. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians; and
- f. health plans, employers, and individual consumers were deprived of the benefits of competition among hospitals.

61. The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, conspiracy, acts and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of August, 2003, issues its Complaint against the Maine Health Alliance and William R. Diggins.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of The Maine Health Alliance (the “Alliance”) and William R. Diggins (hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of the draft of Complaint that counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34 (2003), now in further conformity with the procedure described in Commission Rule 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

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1. Respondent Alliance is a taxable not-for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Maine, and its principal address is 12 Stillwater Avenue, Suite C, Bangor, Maine 04401.
2. Respondent William R. Diggins, an individual, is the Executive Director of the Alliance. His principal address is 12 Stillwater Avenue, Suite C, Bangor, Maine 04401.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent Alliance” means The Maine Health Alliance, its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. “Respondent Diggins” means William R. Diggins.
- C. “Respondents” means Respondent Alliance and Respondent Diggins.
- D. “Hospital” means a health care facility licensed by the State of Maine as a hospital.
- E. “Hospital system” means an organization comprised of two or more hospitals where the same person or persons control each hospital in the organization. For purposes of

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this definition, the definition of the term “control” under 16 C.F.R. § 801.1(b) shall apply. Hospital system includes a hospital that is managed under contract, or is leased, by another hospital.

- F. “Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- G. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- H. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician or hospital services for itself or for any other person. Payor includes any person that develops, leases, or sells access to networks of physicians or hospitals.
- I. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- J. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- K. “Preexisting contract” means a contract that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by Respondent Alliance, pursuant to Paragraph VI.A.2 of this Order, of such payor’s right to terminate such contract.

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- L. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- M. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services, hospital services, or both physician and hospital services in which:
1. all physicians and hospitals who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians and hospitals who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.
- N. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services, hospital services, or both physician and hospital services in which:
1. all physicians and hospitals who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians and hospitals who participate jointly to control costs and improve quality by managing the provision of physician and hospital services such as risk-sharing involving:
 - a. the provision of physician or hospital services to payors at a capitated rate,

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- b. the provision of physician or hospital services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians or hospitals who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by hospitals or physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, when the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:

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1. To negotiate on behalf of any physician with any payor;
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent Alliance;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal with a payor;
- C. Attempting to engage in any action prohibited by Paragraphs II.A or II.B above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.

PROVIDED, HOWEVER, that, nothing in this Paragraph II shall prohibit any agreement involving, or conduct by:

- (i) Respondent Diggins that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice; or

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- (ii) Respondent Alliance, subject to the provisions of Paragraph IV below, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, and so long as the arrangement does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement.

III.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of hospital services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any hospitals:
 - 1. To negotiate on behalf of any hospital with any payor;
 - 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 - 3. Regarding any term, condition, or requirement upon which any hospital deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 - 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent Alliance;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among hospitals concerning any

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hospital's willingness to deal with a payor, or the terms or conditions, including price terms, on which the hospital is willing to deal with a payor;

- C. Attempting to engage in any action prohibited by Paragraphs III.A or III.B above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs III.A through III.C above.

PROVIDED, HOWEVER, that, nothing in this Paragraph III shall prohibit any agreement involving, or conduct by:

- (i) Respondent Diggins that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves hospitals in the same hospital system; or
- (ii) Respondent Alliance, subject to the provisions of Paragraph IV below, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, and so long as the arrangement does not restrict the ability, or facilitate the refusal, of hospitals who participate in it to deal with payors on an individual basis or through any other arrangement.

IV.

IT IS FURTHER ORDERED that:

- A. Respondent Alliance shall, pursuant to each purported qualified risk-sharing joint arrangement or purported qualified clinically-integrated joint arrangement

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(“Arrangement”), for five (5) years from the date this Order becomes final, notify the Secretary of the Commission in writing (“Notification”) at least sixty (60) days prior to:

1. Participating in, organizing, or facilitating any discussion or understanding with or among any physicians or hospitals in such Arrangement relating to price or other terms or conditions of dealing with any payor; or
 2. Contacting a payor, pursuant to an Arrangement to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any payor, on behalf of any physician or hospital in such Arrangement. Notification is not required for negotiations or agreements with subsequent payors pursuant to any Arrangement for which this Notification was given;
- B. Respondent Alliance shall, with respect to any Arrangement, include the following information in the Notification:
1. for each physician, his or her name, address, telephone number, medical specialty and medical practice group, if applicable, and name of each hospital where he or she has privileges;
 2. the name of each hospital and the name and telephone number of the person at each hospital responsible for that hospital’s membership relationship with the Alliance;
 3. a description of the Arrangement, its purpose, function, and area of operation;
 4. a description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;

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5. an explanation of the relationship of any agreement on prices or contract terms related to price to furthering the integration and achieving the efficiencies of the Arrangement;
 6. a description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities;
 7. all studies, analyses, and reports, which were prepared for the purpose of evaluating or analyzing competition for physician or hospital services in any relevant market, including, but not limited to, the market share of physician services in any relevant market, or the market share of hospital services in any relevant market;
- C. If, within sixty (60) days from the Commission's receipt of the Notification, a representative of the Commission makes a written request for additional information, Respondent Alliance shall not engage in any conduct described in Paragraph IV.A prior to the expiration of thirty (30) days after substantially complying with such request for additional information, or such shorter waiting period as may be granted in writing from the Bureau of Competition. The expiration of any waiting period described herein without a request for additional information shall not be construed as a determination by the Commission, or its staff, that a violation of the law, or of this Order, may not have occurred. In addition, the absence of notice to the Alliance that the Arrangement has been rejected, regardless of a request for additional information, shall not be construed as a determination by the Commission, or its staff, that the Arrangement has been approved. Further, receipt by the Commission from the Alliance of any Notification of an Arrangement is not to be construed as a determination by the Commission that any such Arrangement does or does not violate this Order or any law enforced by the Commission, including, but not

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limited to Sections 7 and 7A of the Clayton Act, 15 U.S.C. §§ 18 and 18a.

V.

IT IS FURTHER ORDERED that Respondent Diggins for three (3) years from the date this Order becomes final, directly or indirectly, or through any corporate or other device, in connection with the provision of physician or hospital services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Negotiating with any payor on behalf of any physician or hospital who participates, or has participated, in Respondent Alliance, notwithstanding whether such conduct also is prohibited by Paragraph II or Paragraph III of this Order; and
- B. Advising any physician or hospital who participates, or has participated, in Respondent Alliance to accept or reject any term, condition, or requirement of dealing with any payor, notwithstanding whether such conduct also is prohibited by Paragraph II or Paragraph III of this Order.

PROVIDED, HOWEVER, nothing in this Paragraph V shall prohibit Respondent Diggins from forming, participating in, or taking any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement on behalf of the Alliance.

VI.

IT IS FURTHER ORDERED that Respondent Alliance shall:

- A. Within thirty (30) days after the date on which this Order becomes final:

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1. send by first-class mail, with delivery confirmation, a copy of this Order and the Complaint to:
 - a. each physician and hospital who participates, or has participated, in Respondent Alliance;
 - b. each officer, director, manager, and employee of Respondent Alliance;
 2. send by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the notice specified in Appendix A to this Order to the chief executive officer of each payor that contracts with Respondent Alliance for the provision of physician or hospital services;
- B. Terminate, without penalty or charge, and in compliance with any applicable laws of the State of Maine, any preexisting contract with any payor for the provision of physician or hospital services, at the earlier of: (1) receipt by Respondent Alliance of a written request to terminate such contract from any payor that is a party to the contract; or (2) the termination or renewal date (including any automatic renewal date) of such contract; provided, however, a preexisting contract may extend beyond the termination or renewal date for a maximum of one year if the payor provides written affirmation of the preexisting contract prior to the termination or renewal date, and Respondent Alliance has determined not to exercise its right to terminate pursuant to the terms of the preexisting agreement;
- C. For three (3) years from the date this Order becomes final:
1. Distribute by first-class mail, return receipt requested, a copy of this Order and the Complaint to:
 - a. each physician or hospital who begins participating in Respondent Alliance, and who did not previously

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receive a copy of this Order and the Complaint from Respondent Alliance, within thirty (30) days of the time that such participation begins;

- b. each payor who contracts with Respondent Alliance for the provision of physician or hospital services, and who did not previously receive a copy of this Order and the Complaint from Respondent Alliance, within thirty (30) days of the time that such payor enters into such contract;
 - c. each person who becomes an officer, director, manager, or employee of Respondent Alliance, and who did not previously receive a copy of this Order and the Complaint from Respondent Alliance, within thirty (30) days of the time that he or she assumes such responsibility with Respondent Alliance; and
2. Annually publish in an official annual report or newsletter sent to all physicians and hospitals who participate in Respondent Alliance, a copy of this Order and the Complaint with such prominence as is given to regularly featured articles;
- D. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent Alliance, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries or any other change in Respondent Alliance that may affect compliance obligations arising out of this Order;
- E. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include:

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1. a detailed description of the manner and form in which Respondent Alliance has complied and is complying with this Order;
2. the name, address, and telephone number of each payor with which Respondent Alliance has had any contact; and
3. copies of the delivery confirmations required by Paragraph VI.A.1, and copies of the signed return receipts required by Paragraphs VI.A.2 and VI.C.1.

VII.

IT IS FURTHER ORDERED that Respondent Diggins shall:

- A. For three (3) years from the date this Order becomes final, distribute by first-class mail, return receipt requested, a copy of this Order and the Complaint to:
 1. all physician groups, hospital groups, and physician-hospital organizations, other than any medical group practice or hospital system, that Respondent Diggins represents for the purpose of contracting, or seeking to contract, with payors for the provision of physician or hospital services, or that Respondent Diggins advises with regard to their dealings with payors in connection with the provision of physician or hospital services, within (30) days of the time that Respondent Diggins begins providing such representation or advice, unless such physician group, hospital group, or physician-hospital organization previously received a copy of this Order and the Complaint from Respondent Alliance or Respondent Diggins; and
 2. each payor with which Respondent Diggins deals, or has dealt, for the purpose of contracting, or seeking to contract, while representing or advising any physician

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groups, hospital groups, or physician-hospital organizations, other than any medical group practice or hospital system, with regard to their dealings regarding contracting with such payor for the provision of physician or hospital services, within thirty (30) days of such dealing, unless such payor previously received a copy of this Order and the Complaint from Respondent Alliance or Respondent Diggins;

- B. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth:
1. in detail, the manner and form in which Respondent Diggins has complied and is complying with this Order;
 2. the name, address, and telephone number of each physician, hospital, group of physicians or hospitals, or physician-hospital organization that Respondent Diggins has represented or advised with respect to their dealings with any payor in connection with the provision of physician or hospital services;
 3. the name, address, and telephone number of each payor with which Respondent Diggins has dealt while representing any physician, hospital, group of physicians or hospitals, or physician-hospital organization in connection with the provision of physician or hospital services; and
 4. copies of the signed return receipt required by this Paragraph VII.A.

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VIII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in his or its respective principal address within twenty (20) days of such change in address.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order;
- B. Upon five (5) days' notice to Respondent Alliance, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent Alliance; and
- C. Upon five (5) days' notice to Respondent Diggins, and in the presence of counsel, and without restraint or interference from such Respondent, to interview such Respondent or the employees of such Respondent.

X.

IT IS FURTHER ORDERED that this Order shall terminate on August 27, 2023.

By the Commission, Commissioner Harbour not participating.

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Appendix A

[letterhead of The Maine Health Alliance]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against The Maine Health Alliance.

Pursuant to Paragraph VI.B of the enclosed consent order, the Alliance must allow you, subject to compliance with Maine law, to terminate upon written request, without any penalty or charge, any contracts with the Alliance that were in effect prior to your receipt of this letter.

Paragraph VI.B of the consent order also provides that, if you do not terminate a contract, the contract will terminate on its earliest termination or renewal date (including any automatic renewal date). However, at your request, the contract may be extended to a date no later than [appropriate date to be filled in by Respondent], but only if the Alliance waives its right to terminate the contract.

Any request either to terminate or to extend the contract should be made in writing, and sent to me at the following address:
[address].

Sincerely,

[Executive Director of MHA]
Executive Director
Maine Health Alliance

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with the Maine Health Alliance and its Executive Director, William R. Diggins. The Alliance is an organization consisting of over 325 physicians and 11 hospitals in northeastern Maine. The agreement settles charges that respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among physician members and among hospital members of the Alliance to fix prices and other terms of dealing for physician and hospital services with health insurance firms and other third-party payors, and to refuse to deal with these payors except on collectively determined terms. These price-fixing agreements and concerted refusals to deal among otherwise competing physicians and among otherwise competing hospitals, in turn, have kept the price of health care in northeastern Maine above the level that would have prevailed absent the illegal conduct. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by the respondents that they violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

Analysis

The Complaint Allegations

The Alliance was formed in 1995 by the vast majority of physicians and hospitals in five counties in northeastern Maine to negotiate payor contracts that contained “higher compensation” and more “advantageous” contract terms than the physicians and hospitals could obtain by dealing individually with payors. More than 85% of the physicians on staff at Alliance member hospitals are Alliance members, as are eleven of the sixteen hospitals in the five-county area. The physician and hospital members designated the Alliance as their negotiating agent to contract with payors, and authorized the Alliance to enter into, on their behalf, payor contracts.

Although the Alliance is a nonprofit corporation, and its member hospitals are tax-exempt organizations, a substantial majority of its physician members are for-profit entities. These for-profit physicians play a significant role in the governance of the Alliance and receive pecuniary benefits as a result of their participation. Participating physicians select 11 of the 22 members of the Alliance’s Board of Directors and thus exercise substantial authority over the policies and actions of the Alliance. The participating physicians are therefore “members” of the Alliance within the meaning of Section 4 of the FTC Act, which grants the Commission jurisdiction over nonprofit organizations that carry on business for the profit of their members. Because the Alliance engages in substantial activities that confer pecuniary benefits on these for-profit members, its activities engaged in on behalf of the physician and hospital members fall within the Commission’s jurisdiction.

Alliance physician and hospital members have refused to contract with payors on an individual basis. Instead, the Alliance’s Board of Directors authorized Mr. Diggins to act as a principal negotiating agent with payors on behalf of the collective membership of the Alliance. Mr. Diggins was instrumental in forming the Alliance, coordinating the membership’s collective

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bargaining activity, and negotiating payor contracts on behalf of the collective membership.

As guidance for Mr. Diggins, the Board, in conjunction with its Contracts Committee, compiled written “Contracting Guidelines and Parameters,” setting forth price-related and other competitively significant terms that the Alliance required in order to contract with payors. Mr. Diggins reported the details of negotiations with payors to the Board and the Contracts Committee. Based on the recommendations of Mr. Diggins, and the Contracts Committee, the Board decided whether to accept or reject contracts with payors on behalf of the Alliance’s physician and hospital members.

The Alliance and Mr. Diggins negotiated higher reimbursement for Alliance physician and hospital members, and more advantageous contract language, than the physicians and hospitals could have achieved through individual contracts with payors. Despite a written Alliance policy allowing members to contract independently of the Alliance, in fact the Alliance and Mr. Diggins encouraged the physician and hospital members to contract only through the Alliance, in order to maintain the Alliance’s leverage over payors. Mr. Diggins provided Alliance physician and hospital members with a model letter for them to use to notify payors that they refused to negotiate individually, and that the Alliance would negotiate on their behalf. In response to payors’ requests to contract directly with Alliance physician and hospital members, the members directed payors to the Alliance for contracting.

The Alliance’s and Mr. Diggins’ joint negotiation of fees and other competitively significant terms has not been reasonably related to any efficiency-enhancing integration. Although the Alliance has developed some clinical programs limited primarily to hospital members, none of the Alliance’s clinical activities create any significant degree of interdependence among the physician or hospital participants, nor do the activities create sufficiently substantial potential efficiencies.

Analysis

By orchestrating agreements among Alliance physician members, and hospital members, to deal only on collectively-determined terms, together with refusals to deal with payors that would not meet those terms, respondents have violated Section 5 of the FTC Act.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of the illegal conduct charged in the complaint, while allowing respondents to engage in legitimate conduct that does not impair competition.

The proposed order's specific provisions are as follows:

The proposed order's core prohibitions are contained in Paragraphs II, III, and V. Paragraph II is intended to prevent the Respondents from participating in, or creating, future unlawful agreements for physician services. Paragraph II.A prohibits the Alliance and Mr. Diggins from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through the Alliance.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the respondents from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D proscribes inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

Paragraph III is intended to prevent the Respondents from participating in, or creating, future unlawful agreements for hospital services. Paragraphs III.A through D are identical to Paragraphs II.A through D, except that they apply to the

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Alliance's or Mr. Diggins' actions regarding the provision of hospital, rather than physician, services. This matter is the Commission's first law enforcement action charging an organization with price-fixing and other anticompetitive collusive conduct in the market for hospital services, in violation of Section 5 of the FTC Act. Thus, unlike previous orders involving collective bargaining with health plans, this order bars agreements relating to both physicians and hospitals.

As in other orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. Respondents would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians or competing hospitals, whether a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement."

As defined in the proposed order, a "qualified risk-sharing joint arrangement" possesses two key characteristics. First, all physician or all hospital participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the participants to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A "qualified clinically-integrated joint arrangement," on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, all physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of

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dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

In the event that the Alliance forms a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement, Paragraph IV requires the Alliance to notify the Commission at least 60 days prior to negotiating or entering into agreements with payors, or discussing price or related terms among the participants of the arrangement. Notification is not required for negotiations or agreements with subsequent payors pursuant to any arrangement for which notice was given under Paragraph IV. Paragraph IV.B sets out the information necessary to make the notification complete. Paragraph IV.C establishes the Commission's right to obtain additional information regarding the arrangement.

Paragraph V prohibits Mr. Diggins, for three years, from negotiating with any payor on behalf of any Alliance physician or hospital member, and from advising any Alliance physician or hospital member to accept or reject any term, condition, or requirement of dealing with any payor. Mr. Diggins, however, is permitted to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement on behalf of the Alliance.

Paragraph VI.A requires the Alliance to distribute the complaint and order to all physicians and hospitals who have participated in the Alliance, and to payors that contract with the Alliance. Paragraph VI.B requires the Alliance, at any payor's request and without penalty, to terminate its current contracts with respect to providing physician services. If a payor does request termination, Paragraph VI.B requires the Alliance to terminate the contract on its earliest termination or renewal date. Paragraph VI.B also provides that a contract may extend up to one year beyond the termination or renewal date if the payor affirms the contract in writing and the Alliance does not exercise its right to terminate the contract.

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Paragraph VII.A requires Mr. Diggins to distribute the complaint and order to physician and hospital groups he represents in contracting with payors, and to payors with which he has dealt in contracting while representing any physician or hospital groups.

Paragraphs VII.B through IX of the proposed order impose various obligations on respondents to report or provide access to information to the Commission to facilitate monitoring respondents' compliance with the order.

The proposed order will expire in 20 years.

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IN THE MATTER OF

PHYSICIAN NETWORK CONSULTING, L.L.C., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4094; File No. 0210178
Complaint, August 27, 2003--Decision, August 27, 2003*

This consent order, among other things, prohibits Respondent Professional Orthopedic Services, Inc., which consists of approximately 28 physicians in three Physician Practices (also Respondents) who provide approximately 70 percent of the orthopedic medicine services in the Baton Rouge, Louisiana area; their agent, Respondent Physician Consulting Network; and the agent's managing director, Respondent Michael J. Taylor, from entering into or facilitating any agreement between or among any physicians (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through any arrangement other than Professional Orthopedic Services. The order also prohibits the respondents from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in – or from encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order. The order also, for three years, requires Respondents Physician Network Consulting and Taylor to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts.

Participants

For the Commission: *Linda Blumenreich, Karan Singh, David R. Pender, Jeffrey W. Brennan, Anne R. Schenof, Roberta S. Baruch, Louis Silvia and Mary T. Coleman.*

For the Respondents: *Jerry W. Sullivan, Leef, Gibbs, Sullivan, Dupre & Aldous, L.L.C., and John J. Miles, Ober, Kaler, Grimes & Shriver.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Physician Network Consulting, L.L.C. (“Physician Network Consulting”), Michael J. Taylor, Professional Orthopedic Services, Inc. (“Professional Orthopedic Services”), The Bone and Joint Clinic of Baton Rouge, Inc. (“The Bone and Joint Clinic”), Baton Rouge Orthopaedic Clinic, L.L.C. (“Baton Rouge Orthopaedic Clinic”), and Orthopaedic Surgery Associates of Baton Rouge, L.L.C. (“Orthopaedic Surgery Associates”), hereinafter collectively referred to as “Respondents,” have violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

NATURE OF THE CASE

1. This matter concerns a horizontal agreement among competing physicians to fix prices charged to United HealthCare of Louisiana, Inc. (“United HealthCare”), and to refuse to deal with United HealthCare except on terms to which the physicians collectively agreed. The physicians orchestrated this behavior with and through their independent practice association, Professional Orthopedic Services, and with and through their non-physician agent, Physician Network Consulting. Respondents’ conduct raised the price of orthopedic services in the Baton Rouge, Louisiana, area.

RESPONDENTS

2. Physician Network Consulting is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 3900 N. Causeway Boulevard, Suite 1470, Metairie,

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LA 70002. Physician Network Consulting represents physicians in contract negotiations with health insurance firms and other third-party payors (“payors”). Physician Network Consulting’s client base includes physicians in approximately seven states.

3. Michael J. Taylor is the founder and managing director of Physician Network Consulting. His principal address is located at 3900 N. Causeway Boulevard, Suite 1470, Metairie, LA 70002. Mr. Taylor, operating through Physician Network Consulting, represents physicians in contract negotiations with payors.

4. Professional Orthopedic Services is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 5408 Flanders Drive, Baton Rouge, LA 70808. Professional Orthopedic Services is an independent practice association consisting of approximately 28 physicians who practice orthopedic medicine. Its members provide approximately 70% of the orthopedic medicine services in the Baton Rouge, Louisiana, area.

5. The Bone and Joint Clinic is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 7777 Hennessy Boulevard, Suite 7000, Baton Rouge, LA 70808. The Bone and Joint Clinic is a group practice consisting of approximately 10 physicians. These physicians practice orthopedic medicine for a fee in the Baton Rouge, Louisiana, area, and are members of Professional Orthopedic Services.

6. Baton Rouge Orthopaedic Clinic is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 7443 Picardy Avenue, Baton Rouge, LA 70808. Baton Rouge Orthopaedic Clinic is a group practice consisting of approximately 15 physicians. These physicians practice orthopedic medicine for a fee in the Baton Rouge,

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Louisiana, area, and are members of Professional Orthopedic Services.

7. Orthopaedic Surgery Associates is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 5408 Flanders Drive, Baton Rouge, LA 70808. Respondent Orthopaedic Surgery Associates includes, but is not limited to, Kenneth C. Cranor, M.D., Samuel C. Irwin, M.D., and Charles S. Walker, M.D. During the period of illegal conduct described in the Complaint, Orthopaedic Surgery Associates was a partnership among these three physicians. These physicians practice orthopedic medicine for a fee in the Baton Rouge, Louisiana, area, and are members of Professional Orthopedic Services.

THE FTC HAS JURISDICTION OVER RESPONDENTS

8. Respondents' general business practices, including the acts and practices herein alleged, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**OVERVIEW OF MARKET AND PHYSICIAN
COMPETITION**

9. The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates, through their shareholders, members, and other affiliated physicians, are engaged in the business of providing orthopedic services to patients in the Baton Rouge area. Except to the extent that competition has been restrained as alleged herein, The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates have been, and are now, in competition with each other for the provision of orthopedic services.

10. To be competitively marketable in the Baton Rouge area, a payor's health insurance plan must include in its physician

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network members of Professional Orthopedic Services, including physicians from at least The Bone and Joint Clinic or Baton Rouge Orthopaedic Clinic.

11. Physicians often contract with payors to establish the terms and conditions, including price terms, under which the physicians will render services to the payors' subscribers. Physicians entering into such contracts often agree to lower compensation to obtain access to additional patients made available by the payors' relationship with their subscribers. These contracts may reduce payors' costs, enable them to lower the price of health insurance, and reduce their subscribers' out-of-pocket medical care expenditures.

12. Absent agreements among competing physicians on the terms, including price, on which they will provide services to enrollees in payors' health care plans, competing physicians decide individually whether to enter into payor contracts to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

13. Medicare's Resource Based Relative Value System ("RBRVS") is a system used by the United States Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. In general, payors in the Baton Rouge, Louisiana, area make contract offers to individual physicians or groups at a price level specified as some percentage of the RBRVS fee for a particular year (*e.g.*, "110% of 2003 RBRVS" or "110% of 2003 Medicare").

14. Competing physicians sometimes use a "messenger" to facilitate the establishment of contracts between themselves and payors in ways that do not constitute or facilitate an unlawful agreement on prices and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate prices and other competitively

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significant terms on behalf of the participating physicians. Nor should a messenger facilitate the physicians' coordinated responses to contract offers by, for example, electing not to convey a payor's offer to them based on the messenger's opinion on the appropriateness, or lack thereof, of the offer.

RESPONDENTS CONSPIRED TO FIX THEIR PRICES TO UNITED HEALTHCARE

15. United HealthCare is a payor doing business in the Baton Rouge area. In 2001, the physicians in The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates were under contract with United HealthCare as network participants in United HealthCare's health plans. By letter dated June 29, 2001, United HealthCare notified these and other physicians of a new price schedule to take effect August 1, 2001, pursuant to United HealthCare's contract with its network of physicians in Louisiana. This price schedule would have paid network physicians an estimated 93% to 114% of 2001 RBRVS, depending on the medical procedures performed.

16. Physician Network Consulting coordinated the physicians' response to United HealthCare. On July 9, 2001, Michael J. Taylor of Physician Network Consulting held a conference call with the business managers of The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates, during which the participants discussed jointly terminating their United HealthCare contracts in response to the new price schedule announcement. The same day, The Bone and Joint Clinic and the physicians in Orthopaedic Surgery Associates all sent letters to United HealthCare, terminating their respective United HealthCare contracts effective in 90 days, pursuant to the 90-day termination notice provision contained in the United HealthCare contract. The next day, Baton Rouge Orthopaedic Clinic also sent a letter to United HealthCare, terminating the contract. Thus, within 24 hours of their conference call with Michael Taylor, all the members of Professional Orthopedic Services terminated their United HealthCare contracts, to become effective in October

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2001. On July 11, 2001, the business manager for The Bone and Joint Clinic sent a letter to Mr. Taylor, enclosing “information that you may find helpful in your negotiations on behalf of POS with United Healthcare,” including an “analysis of the proposed fee schedule.”

17. On July 19, 2001, Michael Taylor, in a broadcast fax to the same business managers, provided a form letter that he urged all of them to prepare and deliver to United HealthCare. The form letter advised United HealthCare that the signatory physicians had authorized Physician Network Consulting and its representative “to act as my agent regarding any contracting between United HealthCare and myself,” and told United HealthCare to contact Physician Network Consulting “to affect [sic] a prompt and equitable agreement” with the physicians. On July 23, 2001, The Bone and Joint Clinic and the physicians in Orthopaedic Surgery Associates transferred Mr. Taylor’s form letter onto their respective letterheads and sent them to United HealthCare. Two days later, Baton Rouge Orthopaedic Clinic did the same thing.

18. On July 24, 2001, and over the next two months, Physician Network Consulting negotiated with United HealthCare for higher payments for the Professional Orthopedic Services members. For example, on August 6, 2001, a Physician Network Consulting representative told United HealthCare in a letter that: “As we discussed during last week’s telephone conversation, [we] have been authorized by the member practices of Professional Orthopaedic [sic] Services, a messenger model IPA, to represent these practices in all fee schedule and contract negotiations with United.” The same letter asserted that the physicians required “130%-135% of 2001 Medicare in order to remain profitable” and that “no extension shall be granted” under the physicians’ termination notices unless United HealthCare agreed to pay them a higher price. The letter concluded by stating: “If [United HealthCare] wishes to maintain these orthopaedic practices in your panel, you should arrange your schedule to meet with me so that I can messenger your response to each practice.” Listed on the letter as blind-copy recipients were the business managers of

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The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates.

19. In September 2001, under the threat of impending contract termination, United HealthCare contacted The Bone and Joint Clinic and Baton Rouge Orthopaedic Clinic directly to attempt to negotiate contract terms with at least one of them. Both groups refused to deal directly and unilaterally with United HealthCare. Instead, they demanded that United HealthCare deal for their services with Professional Orthopedic Services, and do so only through their common agent – Mr. Taylor and Physician Network Consulting.

20. On September 28, 2001, Mr. Taylor sent a letter to United HealthCare, in which he stated that he “messengered your last proposal” to The Bone and Joint Clinic and to Baton Rouge Orthopaedic Clinic but that “both groups have rejected” it, and further that “I believe both would favorably entertain” payment of “120% of Current Medicare” so long as “[t]his fee schedule would be available to all members of POS.” Mr. Taylor asserted in the letter that Professional Orthopedic Services “is a messenger IPA” yet gave copies of the letter – including its explicit statement of a price term for all the competing members of Professional Orthopedic Services – to the practice managers of The Bone and Joint Clinic and Baton Rouge Orthopaedic Clinic.

21. In response to Mr. Taylor’s demand, United HealthCare offered 120% of 2001 RBRVS to The Bone and Joint Clinic and Baton Rouge Orthopaedic Clinic, but made no contract offer to the physicians in Orthopaedic Surgery Associates. On October 3, 2001, Mr. Taylor told United HealthCare that he “messengered” this proposal to The Bone and Joint Clinic and to Baton Rouge Orthopaedic Clinic, but was “sorry to report they have declined your offer.” He continued: “However, the groups are countering a contract that is 125% of 2001 Medicare, and includes all members of the IPA. It is agreed that this will be an IPA contract and all members are to be included therein.”

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22. On October 11, 2001, facing imminent contract termination by The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates, United HealthCare was coerced into accepting Mr. Taylor's contract demands. Accordingly, United HealthCare agreed to a contract with all members of Professional Orthopedic Services, and to pay them 125% of 2001 RBRVS.

RESPONDENTS HAVE ENGAGED IN RESTRAINTS OF TRADE

23. The Bone and Joint Clinic, Baton Rouge Orthopaedic Clinic, and Orthopaedic Surgery Associates, acting as a combination of competing physicians through and with Professional Orthopedic Services, and in conspiracy with Physician Network Consulting and Mr. Taylor, have restrained competition by, among other things:

- a. facilitating, negotiating, entering into, and implementing agreements among themselves and Professional Orthopedic Services on price and other competitively significant terms;
- b. refusing to deal with United HealthCare except on collectively agreed-upon terms; and
- c. negotiating prices and other competitively significant terms in a contract with United HealthCare for themselves and Professional Orthopedic Services.

NO SIGNIFICANT EFFICIENCIES JUSTIFY RESPONDENTS' CONDUCT

24. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

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**RESPONDENTS' ACTIONS HAVE HAD SUBSTANTIAL
ANTICOMPETITIVE EFFECTS**

25. Respondents' actions described in Paragraphs 16 through 23 of this Complaint have had, or have tended to have, the effect of restraining trade unreasonably and hindering competition in the provision of orthopedic services in the Baton Rouge area in the following ways, among others:

- a. price and other forms of competition among physician members of Professional Orthopedic Services were unreasonably restrained;
- b. prices for orthopedic services were increased; and
- c. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians.

26. The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of August, 2003, issues its Complaint against Respondents Physician Network Consulting, L.L.C., Michael J. Taylor, Professional Orthopedic Services, Inc., The Bone and Joint Clinic of Baton Rouge, Inc., Baton Rouge Orthopaedic Clinic, L.L.C., and Orthopaedic Surgery Associates of Baton Rouge, L.L.C.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of Physician Network Consulting, L.L.C. (“Physician Network Consulting”), Michael J. Taylor, Professional Orthopedic Services, Inc. (“Professional Orthopedic Services”), The Bone and Joint Clinic of Baton Rouge, Inc. (“The Bone and Joint Clinic”), Baton Rouge Orthopaedic Clinic, L.L.C. (“Baton Rouge Orthopaedic Clinic”), and Orthopaedic Surgery Associates of Baton Rouge, L.L.C. (“Orthopaedic Surgery Associates”), hereinafter collectively referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of the draft of Complaint that counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents (and, for Respondent Orthopaedic Surgery Associates, each physician member), their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents (or, for Respondent Orthopaedic Surgery Associates, each physician member) of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents (or, for Respondent Orthopaedic Surgery Associates, each physician member) that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents (or, for Respondent Orthopaedic Surgery Associates, each physician member) have violated said Act, and that a Complaint

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should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Physician Network Consulting is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 3900 N. Causeway Boulevard, Suite 1470, Metairie, LA 70002.
2. Respondent Michael J. Taylor is the founder and managing director of Physician Network Consulting. His principal address is 3900 N. Causeway Boulevard, Suite 1470, Metairie, LA 70002.
3. Respondent Professional Orthopedic Services is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 5408 Flanders Drive, Baton Rouge, LA 70808.
4. Respondent The Bone and Joint Clinic is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 7777 Hennessy Boulevard, Suite 7000, Baton Rouge, LA 70808.
5. Respondent Baton Rouge Orthopaedic Clinic is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 7443 Picardy Avenue, Baton Rouge, LA 70808.

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6. Respondent Orthopaedic Surgery Associates is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its principal address at 5408 Flanders Drive, Baton Rouge, LA 70808.
7. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents (and, for Respondent Orthopaedic Surgery Associates, each physician member), and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent Physician Network Consulting” means Physician Network Consulting, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Physician Network Consulting, L.L.C., and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. “ Respondent Taylor” means Michael J. Taylor.
- C. “ Respondent Professional Orthopedic Services” means Professional Orthopedic Services, Inc., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Professional Orthopedic Services, Inc., and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.

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- D. “Respondent The Bone and Joint Clinic” means The Bone and Joint Clinic of Baton Rouge, Inc., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by The Bone and Joint Clinic of Baton Rouge, Inc., and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- E. “ Respondent Baton Rouge Orthopaedic Clinic” means Baton Rouge Orthopaedic Clinic, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Baton Rouge Orthopaedic Clinic, L.L.C., and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- F. “ Respondent Orthopaedic Surgery Associates” means Orthopaedic Surgery Associates of Baton Rouge, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Orthopaedic Surgery Associates of Baton Rouge, L.L.C., and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each. Respondent Orthopaedic Surgery Associates includes, but is not limited to, Kenneth C. Cranor, M.D., Samuel C. Irwin, M.D., and Charles S. Walker, M.D. During the period of illegal conduct described in the Complaint, Orthopaedic Surgery Associates was a partnership among these three physicians.
- G. “Respondent Physician Practices” means Respondent The Bone and Joint Clinic, Respondent Baton Rouge Orthopaedic Clinic, and Respondent Orthopaedic Surgery Associates.

Decision and Order

- H. “Respondents” means Respondent Physician Network Consulting, Respondent Taylor, Respondent Professional Orthopedic Services, and Respondent Physician Practices.
- I. “ Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- J. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- K. “Payor” means any person that pays, or arranges for the payment, for all or any part of any physician services for itself or for any other person. Payor includes any person that develops, leases, or sells access to networks of physicians.
- L. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, limited liability companies, unincorporated entities, and governments.
- M. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- N. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- O. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:

Decision and Order

1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- P. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:
1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate jointly to control costs and improve quality by managing the provision of physician services, such as risk-sharing involving:
 - a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of

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treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and

2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 1. To negotiate on behalf of any physician with any payor;
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent Professional Orthopedic Services;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any

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physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal with a payor;

- C. Attempting to engage in any action prohibited by Paragraph II.A or II.B, above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.

PROVIDED, HOWEVER, that, nothing in this Paragraph II shall prohibit any agreement involving, or conduct by:

- (i) Respondent Physician Network Consulting or Respondent Taylor, subject to the provisions of Paragraph IV below, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice;
- (ii) Respondent Professional Orthopedic Services that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, and so long as the arrangement does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement; or
- (iii) A Respondent Physician Practice that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice.

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III.

IT IS FURTHER ORDERED that Respondent Physician Network Consulting and Respondent Taylor, for three (3) years from the date that this Order becomes final, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Negotiating with any payor on behalf of Respondent Professional Orthopedic Services, or any Respondent Physician Practice, notwithstanding whether such conduct also is prohibited by Paragraph II of this Order; and
- B. Advising any physician who participates, or has participated, in Respondent Professional Orthopedic Services, or any Respondent Physician Practice, to accept or reject any term, condition, or requirement of dealing with any payor, notwithstanding whether such conduct also is prohibited by Paragraph II of this Order.

IV.

IT IS FURTHER ORDERED that, for three (3) years from the date this Order becomes final, Respondent Physician Network Consulting and Respondent Taylor shall notify the Secretary of the Commission in writing (“Notification”) at least sixty (60) days prior to entering into any arrangement with any physicians under which Respondent Physician Network Consulting or Respondent Taylor would act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. The Notification shall include the identity of each proposed physician participant; the proposed geographic area in which the proposed arrangement will operate; a copy of any proposed physician participation agreement; a description of the proposed arrangement’s purpose and function; a description of any resulting efficiencies expected to be obtained through the arrangement; and a description of

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procedures to be implemented to limit possible anticompetitive effects, such as those prohibited by this Order. Notification is not required for Respondent Physician Network Consulting's or Respondent Taylor's subsequent acts as a messenger pursuant to an arrangement for which this Notification has been given. Receipt by the Commission from Respondent Physician Network Consulting or Respondent Taylor of any Notification, pursuant to this Paragraph IV, is not to be construed as a determination by the Commission that any action described in such Notification does or does not violate this Order or any law enforced by the Commission.

V.

IT IS FURTHER ORDERED that Respondent Professional Orthopedic Services shall:

- A. Within thirty (30) days after the date on which this Order becomes final, send by first-class mail, with delivery confirmation, a copy of this Order and the Complaint to:
 1. each physician who participates, or has participated, in Respondent Professional Orthopedic Services; and
 2. each officer, director, manager, and employee of Respondent Professional Orthopedic Services;
- B. For three (3) years after the date this Order becomes final:
 1. Distribute by first-class mail, return receipt requested, a copy of this Order and the Complaint to:
 - a. each physician who begins participating in Respondent Professional Orthopedic Services, and who did not previously receive a copy of this Order and the Complaint from Respondent Professional Orthopedic Services, within thirty (30) days of the time that such participation begins;

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- b. each payor that contracts with Respondent Professional Orthopedic Services for the provision of physician services, within thirty (30) days of the time that such payor enters into such contract, excluding arrangements entered into pursuant to a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement;
 - c. each person who becomes an officer, director, manager, or employee of Respondent Professional Orthopedic Services, and who did not previously receive a copy of this Order and the Complaint from Respondent Professional Orthopedic Services, within thirty (30) days of the time that he or she assumes such responsibility with Respondent Professional Orthopedic Services; and
 2. Annually publish a copy of this Order and the Complaint in an official annual report or newsletter sent to all physicians who participate in Respondent Professional Orthopedic Services, with such prominence as is given to regularly featured articles;
- C. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent Professional Orthopedic Services, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries or any other change in Respondent Professional Orthopedic Services that may affect compliance obligations arising out of this Order; and
- D. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include:

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1. a detailed description of the manner and form in which Respondent Professional Orthopedic Services has complied and is complying with this Order;
2. the name, address, and telephone number of each payor with which Respondent Professional Orthopedic Services has had any contact; and
3. copies of the delivery confirmations and return receipts required by Paragraphs V.A and V.B.

VI.

IT IS FURTHER ORDERED that, within thirty (30) days after the date on which this Order becomes final, Respondent Physician Network Consulting shall send a copy of this Order and the Complaint by first-class mail:

- A. With delivery confirmation, to each physician who participates, or has participated, in a physician group represented by Respondent Physician Network Consulting since January 1, 1999, excluding physicians being represented only to provide services pursuant to a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement;
- B. With return receipt requested, to each present and past employee of Respondent Physician Network Consulting, and to each individual who has acted as a contractor for Respondent Physician Network Consulting (1) relating to contracting, or seeking to contract, with payors for the provision of physician services, or (2) relating to advising physicians with regard to their dealings with payors in connection with the provision of physician services; and
- C. With delivery confirmation, to each payor with which Respondent Physician Network Consulting deals or has dealt since January 1, 1999, for the purpose of contracting,

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or seeking to contract, while representing or advising any physician or group of physicians relating to contracting with such payor for the provision of physician services, excluding contracting only for the provision of physician services provided pursuant to a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement.

VII.

IT IS FURTHER ORDERED that Respondent Physician Network Consulting shall:

- A. For three (3) years after the date this Order becomes final, distribute a copy of this Order and the Complaint:
 1. by first-class mail, with delivery confirmation, to all physicians, excluding any physicians only involved in a medical group practice, that Respondent Physician Network Consulting represents relating to contracting, or seeking to contract, with payors for the provision of physician services, or that Respondent Physician Network Consulting advises relating to providing payors with physician services, within (30) days of the time that Respondent Physician Network Consulting begins providing such representation or advice;
 2. by first-class mail, with delivery confirmation, to each payor with which Respondent Physician Network Consulting deals for the purpose of contracting, or seeking to contract, while representing or advising any physician or group of physicians relating to contracting with such payor for the provision of physician services, excluding contracts only for the provision of physician services provided by a medical group practice, within thirty (30) days of such dealing; and
- B. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes

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final, and at such other times as the Commission may by written notice require. Each report shall include:

1. a detailed description of the manner and form in which Respondent Physician Network Consulting has complied and is complying with this Order;
 2. the name, address, and telephone number of each physician that Respondent Physician Network Consulting has represented or advised with respect to his or her dealings with any payor in connection with the provision of physician services, excluding those physician services provided pursuant to a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement;
 3. the name, address, and telephone number of each payor with which Respondent Physician Network Consulting has dealt while representing any physicians in connection with the provision of physician services, excluding those represented pursuant to a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement;
 4. copies of the delivery confirmations and return receipts required by Paragraphs VI and VII.A; and
- C. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent Physician Network Consulting, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, or the creation or dissolution of subsidiaries or any other change in Respondent Physician Network Consulting that may affect compliance obligations arising out of this Order.

VIII.

IT IS FURTHER ORDERED that, if Respondent Physician Network Consulting fails to comply with all or any portion of Paragraphs IV, VI, VII.A.2, VII.B, or VII.C of this Order within

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sixty (60) days of the time set forth in those paragraphs, then Respondent Taylor shall, within thirty (30) days thereafter, comply with those portions of Paragraphs IV, VI, VII.A.2, VII.B, or VII.C of this Order with which Respondent Physician Network Consulting did not comply.

IX.

IT IS FURTHER ORDERED that each Respondent Physician Practice (and, for Respondent Orthopaedic Surgery Associates, each physician member) shall:

- A. Within thirty (30) days after the date on which this Order becomes final, send by first-class mail, return receipt requested, copies of this Order, the Complaint, and the notice specified in Appendix A to this Order, to the Vice President of Network Management for United HealthCare of Louisiana, Inc. ("United HealthCare"); and
- B. Terminate, without penalty or charge, and in compliance with any applicable laws, any contract with United HealthCare upon receipt of a written request to terminate such contract from United HealthCare.

X.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in his, her, or its respective principal address within twenty (20) days of such change in address.

XI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission:

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- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to such Respondent, and in the presence of counsel, and without restraint or interference from it, to interview such Respondent or the officers, directors, and employees of such Respondent.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on August 27, 2023.

By the Commission, Commissioner Harbour not participating.

Decision and Order

Appendix A.

[letterhead of Respondent sending letter]

[date]

[name],
Vice President of Network Management
United HealthCare of Louisiana, Inc.
3838 North Causeway Boulevard
Metairie, Louisiana 70002

Dear [name]:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against Physician Network Consulting, L.L.C., and others.

Pursuant to Paragraph IX of the enclosed consent order, [Respondent] must allow you to terminate, upon your written request, without any penalty or charge, any contracts with [Respondent] that were in effect prior to your receipt of this letter.

Any request to terminate the contract should be made in writing, and sent to me at the following address: [Respondent's address].

Sincerely,

[Respondent]

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with an independent practice association (“IPA”) of physicians who practice orthopedic medicine, its members’ physician practices, their negotiating agent, and the agent’s managing director. The agreement settles charges that the respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by orchestrating and implementing agreements to fix prices and other terms on which they would deal with a payor, and to refuse to deal with that payor except on collectively-determined terms. The respondents named in the complaint are the agent, Physician Network Consulting, L.L.C., and its managing director, Michael J. Taylor; the IPA, Professional Orthopedic Services, Inc.; and the three physician practices whose physicians are members of the IPA, The Bone & Joint Clinic of Baton Rouge, Inc., Baton Rouge Orthopaedic Clinic, L.L.C., and Orthopaedic Surgery Associates of Baton Rouge, L.L.C. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by respondents that they violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

Analysis

The Complaint Allegations

Professional Orthopedic Services consists of approximately 28 physicians who provide approximately 70 percent of the orthopedic medicine services in the Baton Rouge, Louisiana, area. To be competitively marketable in the Baton Rouge area, a payor's health insurance plan must include in its physician network members of Professional Orthopedic Services, including physicians from at least The Bone and Joint Clinic or Baton Rouge Orthopaedic Clinic.

Physician Network Consulting is an agent for Professional Orthopedic Services' members. It represents physicians in contract negotiations with health insurance firms and other third-party payors. Physician Network Consulting's client base includes physicians in approximately seven states. Michael J. Taylor is the founder and managing director of Physician Network Consulting.

As the complaint alleges, this matter involves the fixing of price terms demanded from United HealthCare of Louisiana, Inc., by Professional Orthopedic Services' members. With and through Mr. Taylor, the members agreed to terminate their respective contracts with United. They authorized Physician Network Consulting to be their common agent to negotiate more lucrative price terms with United. Although Physician Network Consulting purported to operate as a "messenger" – that is, an arrangement that does not facilitate horizontal agreements on price – it engaged in various actions that reflected or orchestrated such agreements.¹

¹ Some arrangements can facilitate contracting between physicians and payors without fostering an agreement among competing physicians on fees or fee-related terms. One such approach, sometimes referred to as a "messenger model" arrangement, is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice. *See*

Analysis

According to the complaint, respondents succeeded in coercing United to accept their price demands, and thereby raised the cost of orthopedic services in the Baton Rouge area. Professional Orthopedic Services engaged in no efficiency-enhancing integration sufficient to justify respondents' agreement on price. By orchestrating agreements among Professional Orthopedic Services' members to deal only on collectively-determined terms, and by refusing to deal with United unless it would meet those terms, respondents violated Section 5 of the FTC Act.

The Proposed Consent Order

The proposed order is designed to remedy the illegal conduct charged in the complaint and to prevent its recurrence. It is similar to recent consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise fees they receive from health plans. The order also includes temporary "fencing-in" relief to ensure that the alleged unlawful conduct by respondents does not continue. Respondents Physician Network Consulting and Mr. Taylor conduct business in a number of states, and the order applies to their activities in all such states.

The proposed order's specific provisions are as follows:

Paragraph II. contains the proposed order's core prohibitions against collectively negotiating prices or organizing group boycotts of payors. Paragraph II.A prohibits the respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through any arrangement other than Professional Orthopedic Services.

Analysis

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the respondents from facilitating exchanges of information among physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraphs II.A or II.B. Paragraph II.D proscribes inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

As in other orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations.

First, respondents would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians, whether a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement."

As defined in the proposed order, a "qualified risk-sharing joint arrangement" possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the participants to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A "qualified clinically-integrated joint arrangement," on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any

Analysis

agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Second, because the order is intended to reach agreements among horizontal competitors, Paragraph II would not bar agreements that only involve physicians who are part of the same medical group practice (defined in Paragraph I.I).

Paragraph III, for three years, bars Physician Network Consulting and Mr. Taylor from negotiating with any payor on behalf of the other respondents, and from advising any physician who participates in Professional Orthopedic Services, or advising the respondent Physician Practices (defined in Paragraph I.G), to accept or reject any term, condition, or requirement of dealing with any payor. This temporary “fencing-in” relief will ensure that the alleged unlawful conduct by these respondents does not continue.

Paragraph IV, for three years, requires Physician Network Consulting and Mr. Taylor to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. Paragraph IV sets out the information necessary to make the notification complete.

Paragraph V requires Professional Orthopedic Services to send the complaint and order to all physicians who have participated in Professional Orthopedic Services, and to payors that contract with Professional Orthopedic Services.

Paragraphs VI and VII generally require Physician Network Consulting to distribute the complaint and order to physicians who have participated in any group that has been represented by Physician Network Consulting since January 1, 1999, and each payor with which Physician Network Consulting has dealt since January 1, 1999, for the purpose of contracting.

Analysis

Paragraph VI.B requires Physician Network Consulting to distribute the complaint and order to present and past employees, and to each individual who has acted as a contractor for Physician Network Consulting relating to contracting or advising physicians with regard to their dealings with payors. Paragraph VI.B is intended to ensure that past as well as present employees and contractors of Physician Network Consulting are made aware of the complaint and consent in order to discourage similar illegal conduct.

In the event that Physician Network Consulting fails to comply with the requirements set forth in Paragraphs IV, VI, VII.A.2, VII.B, or VII.C, Mr. Taylor must do so pursuant to Paragraph VIII.

Paragraph IX requires the respondent Physician Practices to terminate any contract with United HealthCare at United HealthCare's request and without penalty.

Paragraphs VII.B, VII.C, X, and XI of the proposed order impose various obligations on respondents to report or provide access to information to the Commission in order to facilitate monitoring respondents' compliance with the order.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

**IOWA MOVERS AND WAREHOUSEMEN'S
ASSOCIATION**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4096; File No. 0210115

Complaint, September 10, 2003--Decision, September 10, 2003

This consent order, among other things, prohibits Respondent Iowa Movers and Warehousemen's Association – an association with, as members, approximately 70 household goods movers that conduct business within the State of Iowa – from filing tariffs that contain collective intrastate rates. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. In addition, the order prohibits the respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases. The order also requires the respondent to cancel all tariffs it has filed that contain intrastate collective rates; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send its members a letter explaining the terms of the order.

Participants

For the Commission: *Dana Abrahamsen, Patrick J. Roach, Richard B. Dagen, John Howell and Mary T. Coleman.*

For the Respondent: *Richard Howe, Howe, Cunningham & Lowe. P.L.C.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Iowa Movers and Warehousemen's Association (hereinafter sometimes referred to as "respondent" or "IMWA"), a corporation, has violated and is now violating the provisions of Section 5 of said Act, and it appearing to the Commission that a

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proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

NATURE OF THE CASE

This matter concerns horizontal agreements among competing household goods movers that, through respondent, file tariffs for intrastate moving services in Iowa. The tariffs contain collective rates and rules that limit the extent to which movers can discount from those rates when charging consumers for moving services. Through these tariffs, the participating movers engage in a horizontal agreement on prices for their services.

RESPONDENT AND ITS MEMBERS

PARAGRAPH 1. Respondent Iowa Movers and Warehousemen's Association is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Iowa, with its office and principal place of business located at 717 E. Court Avenue, Des Moines, Iowa 50309. In 2002 IMWA became a division of the Iowa Motor Truck Association, but it retains its own identity.

PARAGRAPH 2. Respondent is an association organized for and serving its members' interests, including their economic interests, by promoting, fostering, and advancing the household goods moving industry in the State of Iowa. One of the primary functions of respondent is the initiation, preparation, development, dissemination, and filing with the Iowa Department of Transportation's Office of Motor Carrier Services of tariffs and supplements thereto on behalf of and as agent for its members. Said tariffs and supplements contain rates and charges for the intrastate transportation of household goods and for related services, including, among other things, transporting bulky articles; packing cartons and crates; and extra charges for elevator, stair, and long distance carrying of items. (For purposes of this complaint, the term "tariff" means the publication stating the rates of a carrier for the transportation of property between points

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within the State of Iowa, including updates, revisions, and/or amendments, including general rules and regulations.)

PARAGRAPH 3. Pursuant to Iowa state law, each household goods mover is required to file a tariff with the Office of Motor Carrier Services containing the carrier's rates, fares, or charges for the intrastate transportation of household goods. By Iowa law, a household goods mover is not permitted to charge a rate, fare, or charge different from those contained in its tariff or supplements thereto once the Office of Motor Carrier Services has accepted it.

PARAGRAPH 4. Members of respondent are engaged, among other things, in the business of providing transportation and other services for compensation as household goods movers between points within the State of Iowa. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other household goods movers.

PARAGRAPH 5. IMWA's members consist of approximately 70 household goods movers that conduct business within the State of Iowa. IMWA members receive compensation for intrastate moves. Members of IMWA are entitled to and do, among other things, vote for and elect the directors of the association. The control, direction and management of IMWA are vested in the directors, who choose a President, a Secretary, and a Treasurer to carry on the day-to-day administration and management of IMWA. IMWA has one seat on the Iowa Motor Truck Association's Board of Directors.

JURISDICTION

PARAGRAPH 6. The acts and practices of respondent set forth in Paragraph 7 have been and are now in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, and respondent is subject to the jurisdiction of the Federal Trade Commission. Among other things, the aforesaid acts and practices:

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- (A) Affect the flow of substantial sums of money from the federal government, business, and other private parties to the respondent's members for rendering transportation services, which money flows across state lines;
- (B) Affect the purchase and use of equipment and other goods and services by respondent's members that are shipped in interstate commerce;
- (C) Include the use of the United States mail and other instruments of interstate commerce in furthering the agreements described below; and
- (D) Are supported by the receipt of dues and fees for publications and services from out-of-state members and others.⁴

THE CHALLENGED CONDUCT

PARAGRAPH 7. For many years and continuing up to and including the date of the filing of this complaint, respondent, its members, its officers and directors, and others have agreed to engage, and have engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is, was, or may be to unlawfully hinder, restrain, restrict, suppress, or eliminate competition among household goods movers in the intrastate Iowa household goods moving industry.

Pursuant to, and in furtherance of, said agreement and concert of action, respondent, its members and others have engaged and continue to engage in the following acts, policies, and practices, among others:

- (A) Initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, with the purpose or effect of fixing, establishing, stabilizing or otherwise tampering with rates and charges for the

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transportation of household goods between points within the State of Iowa;

(B) Participating in and continuing to participate in the collectively set rates;

(C) Filing collectively set rates with the Office of Motor Carrier Services; and

(D) Initiating, organizing, coordinating, and conducting meetings or providing a forum for any discussion or agreement among competing carriers concerning or affecting rates charged or proposed to be charged for the intrastate transportation of household goods; or otherwise influencing its members to raise their rates, charge the same or uniform rates, or participate or continue to participate in the collectively set rates.

PARAGRAPH 8. The acts and practices of respondent, its members and others, as alleged in Paragraph 7, have had and are now having the effects, among others, of:

(A) Raising, fixing, stabilizing, pegging, maintaining, or otherwise interfering or tampering with the prices of household goods moves;

(B) Restricting, restraining, hindering, preventing, or frustrating price competition in the household goods moving industry; and

(C) Depriving consumers of the benefits of competition.

THE VIOLATION CHARGED

PARAGRAPH 9. The acts, policies and practices of respondent, its members and others, as herein alleged, were and are to the prejudice and injury of the public and constituted and

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constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this tenth day of September, 2003, issues its complaint against IMWA.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the Iowa Movers and Warehousemen’s Association (“IMWA”), hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Iowa Movers and Warehousemen’s Association is a corporation organized and existing under the laws of the State of Iowa with its principal office and place of business at 717 E. Court Avenue, Des Moines, Iowa 50309.

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2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED, that for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "IMWA" means the Iowa Movers and Warehousemen's Association, its officers, executive board, committees, parents (including, but not limited, to the Iowa Motor Truck Association), representatives, agents, employees, successors and assigns;
- B. "Carrier" means a common carrier of property by motor vehicle;
- C. "Intrastate transportation" means the pickup or receipt, transportation and delivery of property hauled between points within the State of Iowa for compensation by a carrier authorized by the Iowa Department of Transportation's Office of Motor Carrier Services to engage therein;
- D. "Member" means any carrier or other person that pays dues or belongs to IMWA or to any successor corporation;
- E. "Tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Iowa, including updates, revisions, and/or amendments, including general rules and regulations;
- F. "Rate" means a charge, payment or price fixed according to a ratio, scale or standard for direct or indirect transportation service;

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- G. "Collective rates" means any rate or charge established under any contract, agreement, understanding, plan, program, combination or conspiracy between two or more competing carriers, or between any two or more carriers and Respondent; and
- H. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

II.

IT IS FURTHER ORDERED that Respondent, a corporation, its successors and assigns, and its officers, agents, representatives, directors and employees, directly or through any corporation, subsidiary, division or other device, shall forthwith cease and desist from entering into and within 120 days after service upon it of this Order cease and desist from adhering to or maintaining, directly or indirectly, any contract, agreement, understanding, plan, program, combination or conspiracy to fix, stabilize, raise, maintain or otherwise interfere or tamper with the rates charged by two or more carriers for the intrastate transportation of property or related services, goods or equipment, including but not limited to:

1. Knowingly preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment;
2. Providing information to any carrier about rate changes considered or made by any other carrier employing the publishing services of Respondent prior to the time at which such rate change becomes a matter of public record;
3. Inviting, coordinating or providing a forum (including publication of an informational bulletin) for any discussion or agreement between or among competing carriers concerning

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rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment;

4. Suggesting, urging, encouraging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided;
5. Maintaining any rate or tariff committee or other entity to consider, pass upon or discuss intrastate rates or rate proposals; and
6. Preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.

III.

IT IS FURTHER ORDERED that Respondent shall, within 120 days after service upon it of this Order:

1. Cancel all tariffs and any supplements thereto on file with the Iowa Department of Transportation's Office of Motor Carrier Services that establish rates for transportation of property or related services, goods or equipment by common carriers in the State of Iowa and take such action as may be necessary to effectuate cancellation and withdrawal;
2. Terminate all previously executed powers of attorney and rate and tariff service agreements, between it and any carrier utilizing its services, authorizing the publication and/or filing of intrastate collective rates within the State of Iowa;
3. Cancel those provisions of its articles of incorporation, by-laws and procedures and every other rule, opinion, resolution, contract or statement of policy that has the purpose or effect of

Decision and Order

permitting, announcing, stating, explaining or agreeing to any business practice enjoined by the terms of this Order; and

4. Amend its by-laws to require members of IMWA to observe the provisions of the Order as a condition of membership in IMWA.

IV.

IT IS FURTHER ORDERED that, within fifteen (15) days after service upon it of this Order, Respondent shall mail or deliver a copy of this Order, under cover of the letter attached hereto as "Appendix," to each current member of Respondent engaged in the transportation of household goods, and for a period of three (3) years from the date of service of this Order, to each new member engaged in the transportation of household goods within ten (10) days of each such member's acceptance by Respondent.

V.

IT IS FURTHER ORDERED that Respondent notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, or any other proposed change in the corporation which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that Respondent shall file a written report within six (6) months of the date of service of this Order, and annually on the anniversary date of the original report for each of the five (5) years thereafter, and at such other times as the Commission may require by written notice to Respondent, setting forth in detail the manner and form in which it has complied with this Order.

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VII.

IT IS FURTHER ORDERED that this Order shall terminate on September 10, 2023.

By the Commission, Commissioner Harbour not participating.

Decision and Order

APPENDIX

(Letterhead of the Iowa Motor Truck Association)

Dear Member:

The Federal Trade Commission has ordered the Iowa Movers and Warehousemen's Association (IMWA) to cease and desist its tariff and collective rate-making activities. A copy of the Commission Opinion and Order is enclosed.

In order that you may readily understand the terms of the Order, we have set forth its essential provisions, although you must realize that the Order itself is controlling, rather than the following explanation of its provisions:

(1) The IMWA is prohibited from engaging in any collective rate-making activities, including the proposal, development or filing of tariffs which contain any collectively formulated rates for intrastate transportation services. Each member carrier must independently set its own rates for transportation of property or related services, goods or equipment between points within the State of Iowa, but may use IMWA as a tariff publishing agent.

(2) IMWA is prohibited from providing a forum for its members for the purpose of discussing rates.

(3) IMWA is prohibited from urging, suggesting, encouraging or in any way attempting to influence the rates members charge for their intrastate transportation services; IMWA may not provide non-public information to any carrier about rate changes ordered by another carrier.

(4) IMWA is prohibited from maintaining any rate or tariff committee which discusses or formulates intrastate rates or rate proposals.

(5) IMWA is given 120 days to cancel all tariffs and tariff

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supplements currently in effect and on file at the Iowa Department of Transportation's Office of Motor Carrier Services which were prepared, developed or filed by IMWA.

(6) IMWA is required to amend its by-laws to require its members to observe the provisions of the Order as a condition of membership in IMWA.

Sincerely yours,

[appropriate IMWA officer]

Enclosure

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with Iowa Movers and Warehousemen's Association ("IMWA" or "Respondent"). The Agreement is for settlement purposes only and does not constitute an admission by IMWA that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

I. The Commission's Complaint

The proposed Complaint alleges that Respondent Iowa Movers and Warehousemen's Association, a corporation, has violated and is now violating Section 5 of the Federal Trade Commission Act. Specifically, the proposed Complaint alleges that Respondent has agreed to engage, and has engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the household goods moving industry.

Respondent is an association organized for and serving its members, which are approximately 70 household goods movers that conduct business within the State of Iowa. In 2002 IMWA became a division of the Iowa Motor Truck Association, but it retains its own identity. One of the primary functions of IMWA is preparing, and filing with the Iowa Department of Transportation's Office of Motor Carrier Services, tariffs and supplements on behalf of its members. These tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services.

The proposed Complaint alleges that Respondent is engaged in initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, which have the purpose or effect of fixing, establishing or stabilizing rates for the

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transportation of household goods in the State of Iowa. The Respondent files uniform rates and the tariffs contain rules that limit the extent to which movers can discount from those rates when charging consumers for moving services.

The proposed Complaint further alleges that Respondent organizes and conducts meetings that provide a forum for discussion or agreement between competing carriers concerning or affecting rates and charges for the intrastate transportation of household goods.

The proposed Complaint further alleges that Respondent's conduct is anticompetitive because it has the effect of raising, fixing, and stabilizing the prices of household goods moves. The acts of Respondent also have the effect of depriving consumers of the benefits of competition.

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the conduct principally by means of a cease and desist order barring Respondent from continuing its practice of filing tariffs containing collective intrastate rates.

Paragraph II of the proposed Order bars Respondent from filing a tariff that contains collective intrastate rates. This provision will terminate Respondent's current practice of filing tariffs that contain intrastate rates that are the product of an agreement among movers in the State of Iowa. This paragraph also prohibits Respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. For example, the order bars Respondent from providing to other carriers certain non-public information.¹ It also bars Respondent from

¹ A state statute requires that carriers make their tariffs available to the public. Iowa Code § 325D.13.

Analysis

maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases.

Paragraph III of the proposed Order requires Respondent to cancel all tariffs that it has filed that contain intrastate collective rates. This provision will ensure that the collective intrastate rates now on file in the State of Iowa will no longer be in force, allowing for competitive rates in future individual mover tariffs. Paragraph III of the proposed Order also requires Respondent to cancel any provisions in its governing documents that permit it to engage in activities barred by the Order.

Paragraph IV of the proposed Order requires Respondent to send to its members a letter explaining the terms of the Order. This will make clear to members that they can no longer engage in collective rate-making activities.

Paragraphs V and VI of the proposed Order require Respondent to inform the Commission of any change in Respondent that could affect compliance with the Order and to file compliance reports with the Commission for a number of years. Paragraph VII of the proposed Order states that the Order will terminate in 20 years.

III. Opportunity for Modification of the Order

Respondent can seek to modify the proposed Order to permit it to engage in collective rate-making if it can demonstrate that the “state action” defense would apply to its conduct.² The state

² 16 C.F.R. § 2.51. Because the State of Iowa recently enacted legislation expanding the state’s authority to review tariff filings, Respondent may seek to modify the Order in this instance. (Senate File 97, signed into law on March 28, 2003.) We note that a change in the statute alone is insufficient to assure active state supervision. As explained below, actual supervision, rather than mere statutory authority to supervise, is required. We discuss the state action defense below in some detail. *See also Indiana*

Analysis

action doctrine dates back to the Supreme Court's 1943 opinion in *Parker v. Brown*, which held that, in light of the States' status as sovereigns, and given basic principles of federalism, Congress would not have intended the Sherman Act to apply to the activities of States themselves.³ The defense also has been interpreted in limited circumstances to shield from antitrust scrutiny private firms' activities that are conducted pursuant to state authority. States may not, however, simply authorize private parties to violate the antitrust laws.⁴ Instead, a State must substitute its own control for that of the market.

Thus, the state action defense would be available to Respondent only if it could demonstrate that its conduct satisfied the strict two-pronged standard the Supreme Court set out in *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*: "the challenged restraint must be 'one clearly articulated and affirmatively expressed as state policy'" and "the policy must be 'actively supervised' by the state itself."⁵

Household Movers and Warehousemen, Inc., File No. 021-0115 (Mar. 18, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf>.

³ 317 U.S. 341 (1943).

⁴ *Parker v. Brown*, 317 U.S. at 351 ("[A] state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or declaring that their action is lawful.").

⁵ 445 U.S. 97, 105 (1980) ("*Midcal*") (quoting *City of Lafayette v. Louisiana Power & Light*, 435 U.S. 389, 410 (1978)). The "restraint" in this instance is the collective rate-setting. This articulation of the state action doctrine was reaffirmed by the Supreme Court in *FTC v. Ticor Title Insurance Co.* ("*Ticor*"), 504 U.S. 621, 633 (1992), where the Court noted that the gravity of the antitrust violation of price fixing requires exceptionally clear

Analysis

Under the first prong of *Midcal*'s two-part test, Respondent would be required to show that the State of Iowa had "clearly articulated and affirmatively expressed as state policy" the desire to replace competition with a regulatory scheme. With regard to this prong, it appears that under Iowa law tariffs must be "just, reasonable, and nondiscriminating."⁶ Respondent would meet its burden only if it could show that this or some other provision of Iowa law constitutes a clear expression of state policy to displace competition and allow for collective rate-making among competitors.

Under the second prong of the *Midcal* test, Respondent would be required to demonstrate "active supervision" by state officials. The Supreme Court has made clear that the active supervision standard is a rigorous one. It is not enough that the State grants general authority for certain business conduct or that it approves private agreements with little review. As the Court held in *Midcal*, "The national policy in favor of competition cannot be thwarted by casting such a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement."⁷ Rather, active supervision is designed to ensure that a private party's anticompetitive action is shielded from antitrust liability only when "the State has effectively made [the challenged] conduct its own."⁸

evidence of the State's decision to supplant competition.

⁶ Iowa Code § 325A.7. In addition, an Iowa administrative rule specifically allows carriers of household goods to file their tariffs through an agent or another motor carrier, suggesting administrative approval of collective rate filings. Iowa Administrative Code 761-524.15(325A).

⁷ *Midcal*, 445 U.S. at 105-06.

⁸ *Patrick v. Burget*, 486 U.S. 94, 106 (1988).

Analysis

In order for state supervision to be adequate for state action purposes, state officials must engage in a “pointed re-examination” of the private conduct.⁹ In this regard, the State must “*have and exercise* ultimate authority” over the challenged anticompetitive conduct.¹⁰ To do so, state officials must exercise “sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.”¹¹ One asserting the state action defense must demonstrate that the state agency has ascertained the relevant facts, examined the substantive merits of the private action, assessed whether that private action comports with the underlying statutory criteria established by the state legislature, and squarely ruled on the merits of the private action in a way sufficient to establish the challenged conduct as a product of deliberate state intervention rather than private choice.

IV. General Characteristics of Active Supervision

At its core, the active supervision requirement serves to identify those responsible for public policy decisions. The clear articulation requirement ensures that, if a State is to displace national competition norms, it must replace them with specific state regulatory standards; a State may not simply authorize private parties to disregard federal laws,¹² but must genuinely substitute an alternative state policy. The active supervision requirement, in turn, ensures that responsibility for the ultimate conduct can properly be laid on the State itself, and not merely on

⁹ *Midcal*, 445 U.S. at 106. *Accord*, *Ticor*, 504 U.S. at 634-35; *Patrick v. Burget*, 486 U.S. at 100-01.

¹⁰ *Patrick v. Burget*, 486 U.S. at 101 (emphases added).

¹¹ *Ticor*, 504 U.S. at 634-35.

¹² *Parker*, 317 U.S. at 351.

Analysis

the private actors. As the Court explained in *Ticor*:

States must accept political responsibility for actions they intend to undertake. . . . Federalism serves to assign political responsibility, not to obscure it. . . . For States which do choose to displace the free market with regulation, our insistence on real compliance with both parts of the *Midcal* test will serve to make clear that the State is responsible for the price fixing it has sanctioned and undertaken to control.¹³

Through the active supervision requirement, the Court furthers the fundamental principle of accountability that underlies federalism by ensuring that, if allowing anticompetitive conduct proves to be unpopular with a State's citizens, the state legislators will not be "insulated from the electoral ramifications of their decisions."¹⁴

In short, clear articulation requires that a State enunciate an affirmative intent to displace competition and to replace it with a stated criterion. Active supervision requires the State to examine individual private conduct, pursuant to that regulatory regime, to ensure that it comports with that stated criterion. Only then can the underlying conduct accurately be deemed that of the State itself, and political responsibility for the conduct fairly be placed with the State.

Accordingly, under the Supreme Court's precedents, to provide meaningful active supervision, a State must (1) obtain sufficient information to determine the actual character of the private conduct at issue, (2) measure that conduct against the legislature's stated policy criteria, and (3) come to a clear decision that the private conduct satisfies those criteria, so as to make the final decision that of the State itself.

¹³ 504 U.S. at 636.

¹⁴ See *New York v. United States*, 505 U.S. 144, 168-69 (1992).

Analysis

V. Standard for Active Supervision

There is no single procedural or substantive standard that the Supreme Court has held a State must adopt in order to meet the active supervision standard. Satisfying the Supreme Court's general standard for active supervision, described above, is and will remain the ultimate test for that element of the state action defense.

Nevertheless, in light of the foregoing principles, the Commission in this Analysis identifies the specific elements of an active supervision regime that it will consider in determining whether the active supervision prong of state action is met in future cases (as well as in any future action brought by Respondent to modify the terms of this proposed Order). They are three: (1) the development of an adequate factual record, including notice and opportunity to be heard; (2) a written decision on the merits; and (3) a specific assessment – both qualitative and quantitative – of how the private action comports with the substantive standards established by the state legislature. All three elements further the central purpose of the active supervision prong by ensuring that responsibility for the private conduct is fairly attributed to the State. Each will be discussed below.

A. Development of an Adequate Factual Record, Including Notice and Opportunity to Be Heard

To meet the test for active state supervision, in this case Respondent would need to show that the State had in place an administrative body charged with the necessary review of filed tariffs and capable of developing an adequate factual record to do so.¹⁵ In *Ticor*, the Court quoted language from earlier lower court

¹⁵ At the time of any request for a modification, Respondent will be required to produce evidence of what the state reviewing agency is likely to do in response to collective rate-making. We recognize that this involves some prediction and uncertainty,

Analysis

cases setting out a list of organizational and procedural characteristics relevant as the “beginning point” of an effective state program:

[T]he state’s program is in place, is staffed and funded, grants to the state officials ample power and the duty to regulate pursuant to declared standards of state policy, is enforceable in the state’s courts, and demonstrates some basic level of activity directed towards seeing that the private actors carry out the state’s policy and not simply their own policy¹⁶

Moreover, that body would need to be capable of compiling, and actually compile, an adequate factual record to assess the nature and impact of the private conduct in question. The precise factual record that would be required would depend on the substantive norm that the State has provided; the critical question is whether the record has sufficient facts for the reviewing body sensibly to determine that the State’s substantive regulatory requirements have been achieved. In the typical case in which the State has articulated a criterion of consumer impact, obtaining reliable, timely, and complete economic data would be central to the regulatory board’s ability to determine if the State’s chosen

particularly when the Respondent requests an order modification on the basis of a state review program that might be authorized but not yet operating, as the Respondent will still be under order. In such cases it may be appropriate for the Respondent to show what the state program is designed, directed, or organized to do. If a particular state agency is already conducting reviews in some related area, evidence of its approach to these tasks will be particularly relevant.

¹⁶ *Ticor*, 504 U.S. at 637 (citations omitted).

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criterion has been satisfied.¹⁷ Timeliness in particular is an ongoing concern; if the private conduct is to remain in place for an extended period of time, then periodic state reviews of that private conduct using current economic data are important to ensure that the restraint remains that of the State, and not of the private actors.

Additionally, in assembling an adequate factual record, the procedural value of notice and opportunity to comment is well established. These procedural elements, which have evolved in various contexts through common law, through state and federal constitutional law, and through Administrative Procedure Act rulemakings,¹⁸ are powerful engines for ensuring that relevant facts – especially those facts that might tend to contradict the proponent’s contentions – are brought to the state decision-maker’s attention.

B. A Written Decision

A second important element the Commission will look to in determining whether there has been active supervision is whether the state board renders its decision in writing. Though not essential, the existence of a written decision is normally the clearest indication that the board (1) genuinely has assessed

¹⁷ As the *Ticor* Court held, “state officials [must] have undertaken the necessary steps to determine the specifics of the price-fixing or ratesetting scheme.” *Id.* at 638.

¹⁸ The Administrative Procedure Act defines a rule, in part, as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” 5 U.S.C. § 551(4). Actions “concerned with the approval of ‘tariffs’ or rate schedules filed by public utilities and common carriers” are typical examples of rulemaking proceedings. E. Gellhorn & R. Levin, *Administrative Law & Process* 300 (1997).

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whether the private conduct satisfies the legislature's stated standards and (2) has directly taken responsibility for that determination. Through a written decision, whether rejecting or (the more critical context) approving particular private conduct that would otherwise violate the federal antitrust laws, the state board would provide analysis and reasoning, and supporting evidence, that the private conduct furthers the legislature's objectives.¹⁹

C. Qualitative and Quantitative Compliance with State Policy Objectives

In determining active supervision, the substance of the State's decision is critical. Its fundamental purpose must be to determine that the private conduct meets the state legislature's stated criteria. Federal antitrust law does not seek to impose federal substantive standards on state decision-making, but it does require that the States – in displacing federal law – meet their own stated standards. As the *Ticor* Court explained:

Our decisions make clear that the purpose of the active supervision inquiry is not to determine whether the State has met some normative standard, such as efficiency, in its regulatory practices. Its purpose is to determine whether the State has exercised sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties. Much as in

¹⁹ A record preserved by other means, such as audio or video recording technology, might also suffice, provided that it demonstrated that the board had (1) genuinely assessed the private conduct and (2) taken direct responsibility. Such an audio or video recording, however, will be an adequate substitute for a written opinion only when it provides a sufficiently transparent and decipherable view of the decision-making proceeding to facilitate meaningful public review and comment.

Analysis

causation inquiries, the analysis asks whether the State has played a substantial role in determining the specifics of the economic policy. The question is not how well state regulation works but whether the anticompetitive scheme is the State's own.²⁰

Thus, a decision by a state board that assesses both qualitatively and quantitatively whether the “details of the rates or prices” satisfy the state criteria ensures that it is the State, and not the private parties, that determines the substantive policy. There should be evidence of the steps the State took in analyzing the rates filed and the criteria it used in evaluating those rates. There should also be evidence showing whether the State independently verified the accuracy of financial data submitted and whether it relied on accurate and representative samples of data. There should be evidence that the State has a thorough understanding of the consequences of the private parties' proposed action. Tariffs, for instance, can be complex, and there should be evidence that the State not only has analyzed the actual rates charged but also has analyzed the complex rules that may directly or indirectly impact the rates contained in the tariff.

If the State has chosen to include in its statute a requirement that the regulatory body evaluate the impact of particular conduct on “competition,” “consumer welfare,” or some similar criterion, then – to meet the standard for active supervision – there should be evidence that the State has closely and carefully examined the likely impact of the conduct on consumers. Because the central purpose of the federal antitrust laws is also to protect competition and consumer welfare,²¹ conduct that would run counter to those

²⁰ *Ticor*, 504 U.S. at 634-35.

²¹ Indeed, consideration of consumer impact is at the heart of “[a] national policy” that preserves “the free market and . . . a system of free enterprise without price fixing or cartels.” *Id.* at 632.

Analysis

federal laws should not be lightly assumed to be consistent with parallel state goals. Especially when, as here, the underlying private conduct alleged is price fixing – which, as the *Ticor* Court noted, is possibly the most “pernicious” antitrust offense²² – a careful consideration of the specific monetary impact on consumers is critical to any assessment of an overall impact on consumer welfare. To the maximum extent practicable, that consideration should include an express quantitative assessment, based on reliable economic data, of the specific likely impact upon consumers.

It bears emphasizing that States need not choose to enact criteria such as promoting “competition” or “consumer welfare” – the central end of federal antitrust law. A State could instead enact some other criterion. Then, the State’s decision would need to assess whether that objective had been met.

On the other hand, if a State does not disavow (either expressly or through the promulgation of wholly contrary regulatory criteria) that consumer welfare is state regulatory policy, it must address consumer welfare in its regulatory analysis. In claiming the state action defense, a respondent would need to demonstrate that the state board, in evaluating arguably anticompetitive conduct, had carefully considered and expressly quantified the likely impact of that conduct on consumers as a central element of deciding whether to approve that conduct.²³

In the present case, Iowa has chosen to give consideration to, among other state interests, the interests of consumers. A state

²² *Id.* at 639 (“No antitrust offense is more pernicious than price fixing.”).

²³ This requirement is based on the principle that the national policy favoring competition “is an essential part of the economic and legal system within which the separate States administer their own laws.” *Id.* at 632.

Analysis

statute prohibits movers from charging “more for the transportation of persons or property than a fair and just rate or charge.”²⁴ Thus, to establish active supervision, Respondent would be obligated to show that the State, prior to approving the rates at issue, performed an analysis and quantification of whether the rates to consumers would be higher than a “fair and just rate.”

VI. Opportunity for Public Comment

The standards of active supervision remain those laid out by the Supreme Court in *Midcal* and its progeny. Those standards have been explained in detail above to further illustrate how they would apply should Respondent seek to modify this proposed Order. Applying these standards, the Commission believes, will further the principles of federalism and accountability enunciated by the Supreme Court, will help clarify for States and private parties the reach of federal antitrust law, and will ultimately redound to the benefit of consumers.

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the proposed Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or to modify their terms in any way.

²⁴ Iowa Code § 325D.13.

Complaint

IN THE MATTER OF

MINNESOTA TRANSPORT SERVICES ASSOCIATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4097; File No. 0210115

Complaint, September 15, 2003--Decision, September 15, 2003

This consent order, among other things, prohibits Respondent Minnesota Transport Services Association – an association with, as members, approximately 89 household goods movers that conduct business within the State of Minnesota – from filing tariffs that contain collective intrastate rates. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. In addition, the order prohibits the respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases. The order also requires the respondent to cancel all tariffs it has filed that contain intrastate collective rates; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send its members a letter explaining the terms of the order.

Participants

For the Commission: *Dana Abrahamsen, Patrick J. Roach,
Richard B. Dagen, John Howell and Mary T. Coleman.*

For the Respondent: *Patrick Williams, Briggs & Morgan P.A.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Minnesota Transport Services Association (hereinafter sometimes referred to as “respondent” or “MTSA”), a corporation, has violated and is now violating the provisions of Section 5 of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

Complaint

PARAGRAPH 1. Respondent Minnesota Transport Services Association is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its office and principal place of business located at 1821 University Avenue, Suite S-213, St. Paul, Minnesota 55104.

PARAGRAPH 2. Respondent is an association organized for and serving its members' interests, including their economic interests, by promoting, fostering, and advancing the household goods moving industry in the State of Minnesota. One of the primary functions of respondent is the initiation, preparation, development, dissemination, and filing with the Minnesota Department of Transportation of tariffs and supplements thereto on behalf of and as agent for its members. Said tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services, including, among other things, transporting bulky articles; packing boxes and crates; and extra charges for elevator, stair, and long distance carrying of items. (For purposes of this complaint, the term "tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Minnesota, including updates, revisions, and/or amendments, including general rules and regulations.)

PARAGRAPH 3. Pursuant to Minnesota state law, each household goods mover is required to file a tariff with the Minnesota Department of Transportation containing the carrier's rates, fares, or charges for the intrastate transportation of household goods.

PARAGRAPH 4. Members of respondent are engaged, among other things, in the business of providing transportation and other services for compensation as household goods movers between points within the State of Minnesota. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other household goods movers.

Complaint

PARAGRAPH 5. The membership of MTSA consists of approximately 89 household goods movers that conduct business within the State of Minnesota. MTSA members receive compensation for intrastate and local moves. Members of MTSA are entitled to and do, among other things, vote for and elect the trustees who elect officers of the association. The control, direction and management of MTSA are vested in the trustees and officers, including a President, several Vice Presidents, a Secretary and a Treasurer to carry on the day-to-day administration and management of MTSA.

PARAGRAPH 6. The acts and practices of respondent set forth in Paragraph 7 have been and are now in or affecting commerce as “commerce” is defined in the Federal Trade Commission Act, as amended, and respondent is subject to the jurisdiction of the Federal Trade Commission. Among other things, the aforesaid acts and practices:

- (A) Affect the flow of substantial sums of money from the federal government, business, and other private parties to the respondent's members for rendering transportation services, which money flows across state lines;
- (B) Affect the purchase and use of equipment and other goods and services by respondent's members that are shipped in interstate commerce;
- (C) Include the use of the United States mail and other instruments of interstate commerce in furthering the agreements described below; and
- (D) Are supported by the receipt of dues and fees for publications and services from out-of-state members and others.

PARAGRAPH 7. For many years and continuing up to and including the date of the filing of this complaint, respondent, its members, its officers and directors, and others have agreed to

Complaint

engage, and have engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is, was, or may be to unlawfully hinder, restrain, restrict, suppress, or eliminate competition among household goods movers in the intrastate Minnesota household goods moving industry.

Pursuant to, and in furtherance of, said agreement and concert of action, respondent, its members and others have engaged and continue to engage in the following acts, policies, and practices, among others:

- (A) Initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, with the purpose or effect of fixing, establishing, stabilizing or otherwise tampering with rates and charges for the transportation of household goods between points within the State of Minnesota;
- (B) Participating in and continuing to participate in the collectively set rates;
- (C) Filing collectively set rates with the Minnesota Department of Transportation; and
- (D) Initiating, organizing, coordinating, and conducting meetings or providing a forum for any discussion or agreement among competing carriers concerning or affecting rates charged or proposed to be charged for the intrastate transportation of household goods; or otherwise influencing its members to raise their rates, charge the same or uniform rates, or participate or continue to participate in the collectively set rates.

PARAGRAPH 8. The acts and practices of respondent, its members and others, as alleged in Paragraph 7, have had and are now having the effects, among others, of:

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- (A) Raising, fixing, stabilizing, pegging, maintaining, or otherwise interfering or tampering with the prices of household goods moves;
- (B) Restricting, restraining, hindering, preventing, or frustrating price competition in the household goods moving industry; and
- (C) Depriving consumers of the benefits of competition.

PARAGRAPH 9. The acts, policies and practices of respondent, its members and others, as herein alleged, were and are to the prejudice and injury of the public and constituted and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifteenth day of September, 2003, issues its complaint against MTSA.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Minnesota Transport Services Association (“MTSA”), hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Minnesota Transport Services Association is a corporation organized and existing under the laws of the State of Minnesota with its principal office and place of business at 1821 University Avenue, Suite S-213, St. Paul, Minnesota 55104.

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2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED, that for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "MTSA" means Minnesota Transport Services Association, its officers, executive board, committees, representatives, agents, employees, successors and assigns;
- B. "Carrier" means a common carrier of property by motor vehicle;
- C. "Intrastate transportation" means the pickup or receipt, transportation and delivery of property hauled between points within the State of Minnesota for compensation by a carrier authorized by the Minnesota Department of Transportation to engage therein;
- D. "Member" means any carrier or other person that pays dues or belongs to MTSA or to any successor corporation;
- E. "Tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Minnesota, including updates, revisions, and/or amendments, including general rules and regulations;
- F. "Rate" means a charge, payment or price fixed according to a ratio, scale or standard for direct or indirect transportation service;

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- G. "Collective rates" means any rate or charge established under any contract, agreement, understanding, plan, program, combination or conspiracy between two or more competing carriers, or between any two or more carriers and Respondent; and
- H. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

II.

IT IS FURTHER ORDERED that Respondent, a corporation, its successors and assigns, and its officers, agents, representatives, directors and employees, directly or through any corporation, subsidiary, division or other device, shall forthwith cease and desist from entering into and within 120 days after service upon it of this Order cease and desist from adhering to or maintaining, directly or indirectly, any contract, agreement, understanding, plan, program, combination or conspiracy to fix, stabilize, raise, maintain or otherwise interfere or tamper with the rates charged by two or more carriers for the intrastate transportation of property or related services, goods or equipment, including but not limited to:

1. Knowingly preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment;
2. Providing information to any carrier about rate changes considered or made by any other carrier employing the publishing services of Respondent prior to the time at which such rate change becomes a matter of public record;
3. Inviting, coordinating or providing a forum (including publication of an informational bulletin) for any discussion or agreement between or among competing carriers concerning

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rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment;

4. Suggesting, urging, encouraging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided;
5. Maintaining any rate or tariff committee or other entity to consider, pass upon or discuss intrastate rates or rate proposals; and
6. Preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.

III.

IT IS FURTHER ORDERED that Respondent shall, within 120 days after service upon it of this Order:

1. Cancel all tariffs and any supplements thereto on file with the Minnesota Department of Transportation that establish collective rates for transportation of property or related services, goods or equipment by common carriers in the State of Minnesota and take such action as may be necessary to effectuate cancellation and withdrawal;
2. Terminate all previously executed powers of attorney and rate and tariff service agreements, between it and any carrier utilizing its services, authorizing the publication and/or filing of intrastate collective rates within the State of Minnesota;
3. Cancel those provisions of its articles of incorporation, by-laws and procedures and every other rule, opinion, resolution, contract or statement of policy that has the purpose or effect of

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permitting, announcing, stating, explaining or agreeing to any business practice enjoined by the terms of this Order; and

4. Amend its by-laws to require members of MTSA to observe the provisions of the Order as a condition of membership in MTSA.

IV.

IT IS FURTHER ORDERED that, within fifteen (15) days after service upon it of this Order, Respondent shall mail or deliver a copy of this Order, under cover of the letter attached hereto as "Appendix," to each current member of Respondent, and for a period of three (3) years from the date of service of this Order, to each new member within ten (10) days of each such member's acceptance by Respondent.

V.

IT IS FURTHER ORDERED that Respondent notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, or any other proposed change in the corporation which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that Respondent shall file a written report within six (6) months of the date of service of this Order, and annually on the anniversary date of the original report for each of the five (5) years thereafter, and at such other times as the Commission may require by written notice to Respondent, setting forth in detail the manner and form in which it has complied with this Order.

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VII.

IT IS FURTHER ORDERED that this Order shall terminate on September 15, 2023.

By the Commission, Commissioner Harbour not participating.

Decision and Order

APPENDIX

(Letterhead of the Minnesota Transport Services Association)

Dear Member:

The Federal Trade Commission has ordered Minnesota Transport Services Association (MTSA) to cease and desist its collective tariff rate-making activities. A copy of the Commission's Decision and Order is enclosed.

In order that you may readily understand the terms of the Order, we have set forth its essential provisions, although you must realize that the Order itself is controlling, rather than the following explanation of its provisions:

(1) MTSA is prohibited from engaging in any collective rate-making activities, including the proposal, development or filing of tariffs which contain any collectively formulated rates for intrastate transportation services. Each member carrier must independently set its own rates for transportation of property or related services, goods or equipment between points within the State of Minnesota but may use MTSA as a tariff publishing agent for members' independently established rates.

(2) MTSA is prohibited from providing a forum for its members for the purpose of discussing rates.

(3) MTSA is prohibited from urging, suggesting, encouraging or in any way attempting to influence the rates members charge for their intrastate transportation services; MTSA may not provide non-public information to any carrier about rate changes ordered by another carrier.

(4) MTSA is prohibited from maintaining any rate or tariff committee which discusses or formulates intrastate rates or rate proposals.

Decision and Order

(5) MTSA is given 120 days to cancel all tariffs and tariff supplements containing collective rates currently in effect and on file at the Minnesota Department of Transportation which were prepared, developed or filed by MTSA.

(6) MTSA is required to amend its by-laws to require its members to observe the provisions of the Order as a condition of membership in MTSA.

Sincerely yours,

[appropriate MTSA officer]

Enclosure

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with Minnesota Transport Services Association (“MTSA” or “Respondent”). The Agreement is for settlement purposes only and does not constitute an admission by MTSA that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

I. The Commission’s Complaint

The proposed Complaint alleges that Respondent Minnesota Transport Services Association, a corporation, has violated and is now violating Section 5 of the Federal Trade Commission Act. Specifically, the proposed Complaint alleges that Respondent has agreed to engage, and has engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the household goods moving industry.

Respondent is an association organized for and serving its members, which are approximately 89 household goods movers that conduct business within the State of Minnesota. One of the primary functions of Respondent is preparing, and filing with the Minnesota Department of Transportation, tariffs and supplements on behalf of its members. These tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services.

The proposed Complaint alleges that Respondent is engaged in initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, which have the purpose or effect of fixing, establishing or stabilizing rates for the transportation of household goods in the State of Minnesota.

Analysis

The proposed Complaint further alleges that Respondent organizes and conducts meetings that provide a forum for discussion or agreement between competing carriers concerning or affecting rates and charges for the intrastate transportation of household goods.

The proposed Complaint further alleges that Respondent's conduct is anticompetitive because it has the effect of raising, fixing, and stabilizing the prices of household goods moves. The acts of Respondent also have the effect of depriving consumers of the benefits of competition.

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the conduct principally by means of a cease and desist order barring Respondent from continuing its practice of filing tariffs containing collective intrastate rates.

Paragraph II of the proposed Order bars Respondent from filing a tariff that contains collective intrastate rates. This provision will terminate Respondent's current practice of filing tariffs that contain intrastate rates that are the product of an agreement among movers in the State of Minnesota. This paragraph also prohibits Respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. For example, the order bars Respondent from providing to other carriers certain non-public information.¹ It also bars Respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases.

¹ Under a state statute, a carrier's tariff filing "constitutes notice to the public" of the contents of the tariff. MINN. STAT. ANN. § 221.161(Subd. 1).

Analysis

Paragraph III of the proposed Order requires Respondent to cancel all tariffs that it has filed that contain intrastate collective rates. This provision will ensure that the collective intrastate rates now on file in the State of Minnesota will no longer be in force, allowing for competitive rates in future individual mover tariffs. Paragraph III of the proposed Order also requires Respondent to cancel any provisions in its governing documents that permit it to engage in activities barred by the Order.

Paragraph IV of the proposed Order requires Respondent to send to its members a letter explaining the terms of the Order. This will make clear to members that they can no longer engage in collective rate-making activities.

Paragraphs V and VI of the proposed Order require Respondent to inform the Commission of any change in Respondent that could affect compliance with the Order and to file compliance reports with the Commission for a number of years. Paragraph VII of the proposed Order states that the Order will terminate in 20 years.

III. Opportunity for Modification of the Order

Respondent can seek to modify the proposed Order to permit it to engage in collective rate-making if it can demonstrate that the “state action” defense would apply to its conduct.² The state action doctrine dates back to the Supreme Court’s 1943 opinion in *Parker v. Brown*, which held that, in light of the States’ status as sovereigns, and given basic principles of federalism, Congress would not have intended the Sherman Act to apply to the activities

² 16 C.F.R. § 2.51. Because of this possibility, and because the issues raised by this case frequently arise, it is appropriate to address the state action defense in some detail as we did in *Indiana Household Movers and Warehousemen, Inc.*, File No. 021-0115 (Mar. 18, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf>

Analysis

of States themselves.³ The defense also has been interpreted in limited circumstances to shield from antitrust scrutiny private firms' activities that are conducted pursuant to state authority. States may not, however, simply authorize private parties to violate the antitrust laws.⁴ Instead, a State must substitute its own control for that of the market.

Thus, the state action defense would be available to Respondent only if it could demonstrate that its conduct satisfied the strict two-pronged standard the Supreme Court set out in *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*: “the challenged restraint must be ‘one clearly articulated and affirmatively expressed as state policy’” and “the policy must be ‘actively supervised’ by the state itself.”⁵

Under the first prong of *Midcal*'s two-part test, Respondent would be required to show that the State of Minnesota had “clearly articulated and affirmatively expressed as state policy” the desire to replace competition with a regulatory scheme. With regard to this prong, a Minnesota statute in effect until recently specifically addressed collective rates:

³ 317 U.S. 341 (1943).

⁴ *Parker v. Brown*, 317 U.S. at 351 (“[A] state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or declaring that their action is lawful.”).

⁵ 445 U.S. 97, 105 (1980) (“*Midcal*”) (quoting *City of Lafayette v. Louisiana Power & Light*, 435 U.S. 389, 410 (1978)). The “restraint” in this instance is the collective rate-setting. This articulation of the state action doctrine was reaffirmed by the Supreme Court in *FTC v. Ticor Title Insurance Co.* (“*Ticor*”), 504 U.S. 621, 633 (1992), where the Court noted that the gravity of the antitrust violation of price fixing requires exceptionally clear evidence of the State's decision to supplant competition.

Analysis

In order to ensure nondiscriminatory rates and charges for shippers and receivers, the board shall establish a collective rate-making procedure which will ensure the publication and maintenance of just and reasonable rates and charges under uniform, reasonably related rate structures.⁶

On June 8, 2003 this statute was repealed.⁷ With this statute repealed, Respondent would meet its burden only if it could show that some other provision of Minnesota law constitutes a clear expression of state policy to displace competition and allow for collective rate-making among competitors.

Respondent has asserted that the majority of its members were essentially compelled to file collective tariffs with the state because the state statute contemplated granting exemptions from filing collective rates only under limited circumstances.⁸ The repeal of the Minnesota collective rate statute moots this issue in this case. However, even assuming a state statute compels private entities to file collective rates, this would not remove anticompetitive conduct from potential federal antitrust liability. The Supreme Court has made clear that where a state statute compels a private party to engage in a *per se* violation of the federal antitrust laws in order to comply with the state statute, the state statute will be pre-empted by the federal Sherman Act unless

⁶ MINN. STAT. ANN. § 221.165.

⁷ H.F. 1214, 83rd Leg. (MINN. 2003-2004).

⁸ MINN. STAT. ANN. § 221.165; Minnesota Administrative Rule § 8900.1000 (Subpart 2) (exemption can be granted if the mover “will suffer no hardship in publishing its own rates,” the grant will “not conflict with the legislative purpose to be accomplished by commissioner approval of collective ratemaking” and “the grant will be consistent with the public interest”). There is no evidence that the movers participating in the collective tariffs sought exemptions.

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the requirements of the state action doctrine have been met. *Rice v. Norman Williams Co.*, 458 U.S. 654, 661 (1982).⁹ If a state statute compelled competitors to file collective rates, it would be mandating horizontal price fixing, which is the classic *per se* violation of the Sherman Act. If a state chooses to compel such facially anticompetitive private conduct, the private parties are free from federal antitrust liability only when the requirements of the state action doctrine have been met, including active supervision by the state of the private collective rate-setting.¹⁰

Under the second prong of the *Midcal* test, Respondent would be required to demonstrate “active supervision” by state officials. The Supreme Court has made clear that the active supervision standard is a rigorous one. It is not enough that the State grants general authority for certain business conduct or that it approves

⁹ A state statute may be “condemned under the antitrust laws . . . if it mandates or authorizes conduct that necessarily constitutes a violation of the law in all cases, or if it places irresistible pressure on a private party to violate the antitrust laws in order to comply with the statute. Such condemnation will follow under § 1 of the Sherman Act when the conduct contemplated by the statute is in all cases a *per se* antitrust violation.” *Rice*, 458 U.S. at 661.

¹⁰ As the Supreme Court itself noted in *Rice v. Norman Williams Co.*, its earlier decision in *Midcal*, articulating the two prongs of the state action doctrine, overturned a statute that “required members of the California wine industry to file fair trade contracts or price schedules with the State, and provided that if a wine producer had not set prices through a fair trade contract, wholesalers *must* post a resale price schedule for that producer’s brands.” 458 U.S. at 659 (emphasis in original). Thus, the statute at issue in *Midcal* “facially conflicted with the Sherman Act because it *mandated* resale price maintenance, an activity that has long been regarded as a *per se* violation of the Sherman Act.” *Id.* at 659-60 (emphasis in original).

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private agreements with little review. As the Court held in *Midcal*, “The national policy in favor of competition cannot be thwarted by casting such a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement.”¹¹ Rather, active supervision is designed to ensure that a private party’s anticompetitive action is shielded from antitrust liability only when “the State has effectively made [the challenged] conduct its own.”¹²

In order for state supervision to be adequate for state action purposes, state officials must engage in a “pointed re-examination” of the private conduct.¹³ In this regard, the State must “have and exercise ultimate authority” over the challenged anticompetitive conduct.¹⁴ To do so, state officials must exercise “sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.”¹⁵ One asserting the state action defense must demonstrate that the state agency has ascertained the relevant facts, examined the substantive merits of the private action, assessed whether that private action comports with the underlying statutory criteria established by the state legislature, and squarely ruled on the merits of the private action in a way sufficient to establish the challenged conduct as a product of deliberate state intervention rather than private choice.

IV. General Characteristics of Active Supervision

¹¹ *Midcal*, 445 U.S. at 105-06.

¹² *Patrick v. Burget*, 486 U.S. 94, 106 (1988).

¹³ *Midcal*, 445 U.S. at 106. *Accord*, *Ticor*, 504 U.S. at 634-35; *Patrick v. Burget*, 486 U.S. at 100-01.

¹⁴ *Patrick v. Burget*, 486 U.S. at 101 (emphases added).

¹⁵ *Ticor*, 504 U.S. at 634-35.

Analysis

At its core, the active supervision requirement serves to identify those responsible for public policy decisions. The clear articulation requirement ensures that, if a State is to displace national competition norms, it must replace them with specific state regulatory standards; a State may not simply authorize private parties to disregard federal laws,¹⁶ but must genuinely substitute an alternative state policy. The active supervision requirement, in turn, ensures that responsibility for the ultimate conduct can properly be laid on the State itself, and not merely on the private actors. As the Court explained in *Ticor*:

States must accept political responsibility for actions they intend to undertake. . . . Federalism serves to assign political responsibility, not to obscure it. . . . For States which do choose to displace the free market with regulation, our insistence on real compliance with both parts of the *Midcal* test will serve to make clear that the State is responsible for the price fixing it has sanctioned and undertaken to control.¹⁷

Through the active supervision requirement, the Court furthers the fundamental principle of accountability that underlies federalism by ensuring that, if allowing anticompetitive conduct proves to be unpopular with a State's citizens, the state legislators will not be "insulated from the electoral ramifications of their decisions."¹⁸

In short, clear articulation requires that a State enunciate an affirmative intent to displace competition and to replace it with a

¹⁶ *Parker*, 317 U.S. at 351.

¹⁷ 504 U.S. at 636.

¹⁸ See *New York v. United States*, 505 U.S. 144, 168-69 (1992).

Analysis

stated criterion. Active supervision requires the State to examine individual private conduct, pursuant to that regulatory regime, to ensure that it comports with that stated criterion. Only then can the underlying conduct accurately be deemed that of the State itself, and political responsibility for the conduct fairly be placed with the State.

Accordingly, under the Supreme Court's precedents, to provide meaningful active supervision, a State must (1) obtain sufficient information to determine the actual character of the private conduct at issue, (2) measure that conduct against the legislature's stated policy criteria, and (3) come to a clear decision that the private conduct satisfies those criteria, so as to make the final decision that of the State itself.

V. Standard for Active Supervision

There is no single procedural or substantive standard that the Supreme Court has held a State must adopt in order to meet the active supervision standard. Satisfying the Supreme Court's general standard for active supervision, described above, is and will remain the ultimate test for that element of the state action defense.

Nevertheless, in light of the foregoing principles, the Commission in this Analysis identifies the specific elements of an active supervision regime that it will consider in determining whether the active supervision prong of state action is met in future cases (as well as in any future action brought by Respondent to modify the terms of this proposed Order). They are three: (1) the development of an adequate factual record, including notice and opportunity to be heard; (2) a written decision on the merits; and (3) a specific assessment – both qualitative and quantitative – of how the private action comports with the substantive standards established by the state legislature. All three elements further the central purpose of the active supervision prong by ensuring that responsibility for the private conduct is fairly attributed to the State. Each will be discussed below.

Analysis

**A. Development of an Adequate Factual Record,
Including Notice and Opportunity to Be Heard**

To meet the test for active state supervision, in this case Respondent would need to show that the State had in place an administrative body charged with the necessary review of filed tariffs and capable of developing an adequate factual record to do so.¹⁹ In *Ticor*, the Court quoted language from earlier lower court cases setting out a list of organizational and procedural characteristics relevant as the “beginning point” of an effective state program:

[T]he state’s program is in place, is staffed and funded, grants to the state officials ample power and the duty to regulate pursuant to declared standards of state policy, is enforceable in the state’s courts, and demonstrates some basic level of activity directed towards seeing that the private actors carry out the state’s policy and not simply their own policy²⁰

¹⁹ At the time of any request for a modification, Respondent will be required to produce evidence of what the state reviewing agency is likely to do in response to collective rate-making. We recognize that this involves some prediction and uncertainty, particularly when the Respondent requests an order modification on the basis of a state review program that might be authorized but not yet operating, as the Respondent will still be under order. In such cases it may be appropriate for the Respondent to show what the state program is designed, directed, or organized to do. If a particular state agency is already conducting reviews in some related area, evidence of its approach to these tasks will be particularly relevant.

²⁰ *Ticor*, 504 U.S. at 637 (citations omitted).

Analysis

Moreover, that body would need to be capable of compiling, and actually compile, an adequate factual record to assess the nature and impact of the private conduct in question. The precise factual record that would be required would depend on the substantive norm that the State has provided; the critical question is whether the record has sufficient facts for the reviewing body sensibly to determine that the State's substantive regulatory requirements have been achieved. In the typical case in which the State has articulated a criterion of consumer impact, obtaining reliable, timely, and complete economic data would be central to the regulatory board's ability to determine if the State's chosen criterion has been satisfied.²¹ Timeliness in particular is an ongoing concern; if the private conduct is to remain in place for an extended period of time, then periodic state reviews of that private conduct using current economic data are important to ensure that the restraint remains that of the State, and not of the private actors.

Additionally, in assembling an adequate factual record, the procedural value of notice and opportunity to comment is well established. These procedural elements, which have evolved in various contexts through common law, through state and federal constitutional law, and through Administrative Procedure Act rulemakings,²² are powerful engines for ensuring that relevant

²¹ As the *Ticor* Court held, "state officials [must] have undertaken the necessary steps to determine the specifics of the price-fixing or ratesetting scheme." *Id.* at 638.

²² The Administrative Procedure Act defines a rule, in part, as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Actions "concerned with the approval of 'tariffs' or rate schedules filed by public utilities and common carriers" are typical examples of rulemaking proceedings. E. Gellhorn & R. Levin, *Administrative Law & Process* 300 (1997).

Analysis

facts – especially those facts that might tend to contradict the proponent’s contentions – are brought to the state decision-maker’s attention.

B. A Written Decision

A second important element the Commission will look to in determining whether there has been active supervision is whether the state board renders its decision in writing. Though not essential, the existence of a written decision is normally the clearest indication that the board (1) genuinely has assessed whether the private conduct satisfies the legislature’s stated standards and (2) has directly taken responsibility for that determination. Through a written decision, whether rejecting or (the more critical context) approving particular private conduct that would otherwise violate the federal antitrust laws, the state board would provide analysis and reasoning, and supporting evidence, that the private conduct furthers the legislature’s objectives.²³

C. Qualitative and Quantitative Compliance with State Policy Objectives

In determining active supervision, the substance of the State’s decision is critical. Its fundamental purpose must be to determine that the private conduct meets the state legislature’s stated criteria. Federal antitrust law does not seek to impose federal substantive standards on state decision-making, but it does require that the

²³ A record preserved by other means, such as audio or video recording technology, might also suffice, provided that it demonstrated that the board had (1) genuinely assessed the private conduct and (2) taken direct responsibility. Such an audio or video recording, however, will be an adequate substitute for a written opinion only when it provides a sufficiently transparent and decipherable view of the decision-making proceeding to facilitate meaningful public review and comment.

Analysis

States – in displacing federal law – meet their own stated standards. As the *Ticor* Court explained:

Our decisions make clear that the purpose of the active supervision inquiry is not to determine whether the State has met some normative standard, such as efficiency, in its regulatory practices. Its purpose is to determine whether the State has exercised sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties. Much as in causation inquiries, the analysis asks whether the State has played a substantial role in determining the specifics of the economic policy. The question is not how well state regulation works but whether the anticompetitive scheme is the State's own.²⁴

Thus, a decision by a state board that assesses both qualitatively and quantitatively whether the “details of the rates or prices” satisfy the state criteria ensures that it is the State, and not the private parties, that determines the substantive policy. There should be evidence of the steps the State took in analyzing the rates filed and the criteria it used in evaluating those rates. There should also be evidence showing whether the State independently verified the accuracy of financial data submitted and whether it relied on accurate and representative samples of data. There should be evidence that the State has a thorough understanding of the consequences of the private parties' proposed action. Tariffs, for instance, can be complex, and there should be evidence that the State not only has analyzed the actual rates charged but also has analyzed the complex rules that may directly or indirectly impact the rates contained in the tariff.

If the State has chosen to include in its statute a requirement that the regulatory body evaluate the impact of particular conduct

²⁴ *Ticor*, 504 U.S. at 634-35.

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on “competition,” “consumer welfare,” or some similar criterion, then – to meet the standard for active supervision – there should be evidence that the State has closely and carefully examined the likely impact of the conduct on consumers. Because the central purpose of the federal antitrust laws is also to protect competition and consumer welfare,²⁵ conduct that would run counter to those federal laws should not be lightly assumed to be consistent with parallel state goals. Especially when, as here, the underlying private conduct alleged is price fixing – which, as the *Ticor* Court noted, is possibly the most “pernicious” antitrust offense²⁶ – a careful consideration of the specific monetary impact on consumers is critical to any assessment of an overall impact on consumer welfare. To the maximum extent practicable, that consideration should include an express quantitative assessment, based on reliable economic data, of the specific likely impact upon consumers.

It bears emphasizing that States need not choose to enact criteria such as promoting “competition” or “consumer welfare” – the central end of federal antitrust law. A State could instead enact some other criterion. Then, the State’s decision would need to assess whether that objective had been met.

On the other hand, if a State does not disavow (either expressly or through the promulgation of wholly contrary regulatory criteria) that consumer welfare is state regulatory policy, it must address consumer welfare in its regulatory analysis. In claiming the state action defense, a respondent would need to demonstrate that the state board, in evaluating arguably anticompetitive conduct, had

²⁵ Indeed, consideration of consumer impact is at the heart of “[a] national policy” that preserves “the free market and . . . a system of free enterprise without price fixing or cartels.” *Id.* at 632.

²⁶ *Id.* at 639 (“No antitrust offense is more pernicious than price fixing.”).

Analysis

carefully considered and expressly quantified the likely impact of that conduct on consumers as a central element of deciding whether to approve that conduct.²⁷

In the present case, Minnesota has chosen to give consideration to, among other state interests, the interests of consumers. Statutes require that the rates not be "unjust, unreasonable, unjustly discriminatory, unduly preferential or prejudicial"²⁸ and that they not be "excessive."²⁹ Thus, to establish active supervision, Respondent would be obligated to show that the State, prior to approving the rates at issue, performed an analysis and quantification of whether the rates to consumers are "excessive."

VI. Opportunity for Public Comment

The standards of active supervision remain those laid out by the Supreme Court in *Midcal* and its progeny. Those standards have been explained in detail above to further illustrate how they would apply should Respondent seek to modify this proposed Order. Applying these standards, the Commission believes, will further the principles of federalism and accountability enunciated by the Supreme Court, will help clarify for States and private parties the reach of federal antitrust law, and will ultimately redound to the benefit of consumers.

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons.

²⁷ This requirement is based on the principle that the national policy favoring competition "is an essential part of the economic and legal system within which the separate States administer their own laws." *Id.* at 632.

²⁸ MINN. STAT. ANN. § 221.161(Subd. 1).

²⁹ MINN. STAT. ANN. § 221.161(Subd. 2).

Analysis

Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the proposed Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or to modify their terms in any way.

Complaint

IN THE MATTER OF

SOUTH GEORGIA HEALTH PARTNERS, L.L.C., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4100; File No. 0110222**Complaint, October 31, 2003--Decision, October 31, 2003*

This consent order, among other things, prohibits Respondent South Georgia Health Partners, L.L.C. ("SGHP") -- a for-profit organization whose members include approximately 500 physicians and 15 hospitals -- and eight other respondents, including five other physician-hospital organizations; and three independent practice associations, from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten to refuse to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than respondents. The order also prohibits the respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in, or from inducing anyone to engage in, any action prohibited by the order. The order also requires a respondent that has formed certain types of arrangements to notify the Commission at least 60 days prior to negotiating or entering into agreements with payors or discussing price or related terms among the participants of the arrangement, and requires the respondents to notify certain payors that any contract with SGHP may be terminated at the payor's written request.

Participants

For the Commission: *Steven J. Osnowitz, Jerod T. Klein, Pamela L. Timus, Emily R. Pitlick, David R. Pender, Jeffrey W. Brennan, Anne R. Schenof, Roberta S. Baruch, Fred Martin Louis Silvia and Mary T. Coleman.*

For the Respondents: *Jeffrey Spigel, King & Spalding and David Robbins, Duane Morris.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that South Georgia Health Partners, L.L.C. (“SGHP”); Coastal Plains Health Alliance, L.L.C. (“Coastal Plains Health Alliance”); Colquitt County PHO, L.L.C. (“Colquitt County PHO”); Colquitt County Physicians Association, L.L.C. (“Colquitt County Physicians”); Georgia/Florida Preferred, L.L.C., dba Health Alliance of the South (“Health Alliance of the South”); Qualicare Physicians Association, L.L.C. (“Qualicare Physicians Association”); Satilla HealthNet, Inc. (“Satilla HealthNet”); South Georgia PHO, L.L.C. (“South Georgia PHO”); and South Georgia Physician Network, L.L.C. (“South Georgia Physician Network”); hereinafter referred to as “Respondents,” have violated and are violating Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

NATURE OF THE CASE

1. Fifteen hospitals and approximately 500 physicians in a large region of south Georgia have agreed to restrain competition by collectively setting the price and other terms of contracts that they enter into with employers, health insurers, and others that seek to provide health care coverage in that area (“payors”). Respondents have jointly refused to deal individually with payors not willing to meet Respondents' collective terms. These price-fixing agreements and concerted refusals to deal among competing hospitals and competing physicians have raised the cost of health care in south Georgia. Respondents have not shared substantial financial risk in their provision of physician or hospital services and have not integrated their practices in any other way, so as to justify their collective pricing agreements.

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SOUTH GEORGIA HEALTH PARTNERS, L.L.C.

2. SGHP is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 160 East Second Street, Tifton, Georgia 31794. SGHP represents hospitals and physicians in the negotiation of contracts with payors, pursuant to which the payors compensate the hospitals and physicians for the services that they provide to enrollees in the payors' health care plans.

3. SGHP is the type of organization that is sometimes referred to as a "physician-hospital organization" or "PHO." Five other PHOs (the "Owner PHOs") jointly own and are part of SGHP. As such, SGHP is sometimes also referred to as a "Super PHO." Each Owner PHO has multiple physician members and at least one hospital; in total, the Owner PHOs include 10 hospitals. Physician members in three of the Owner PHOs are also organized into independent practice associations (the "IPA Respondents").

4. Five hospitals in south Georgia, although not members of any Owner PHO, are members of SGHP and enter into payor contracts that SGHP negotiates on their collective behalf. These hospitals are: Bacon County Hospital in Alma; Berrien County Hospital in Nashville; Donalsonville Hospital in Donalsonville; Dorminy Medical Center in Fitzgerald; and Memorial Hospital in Adel.

5. SGHP has as members approximately 500 physicians and 15 hospitals that, collectively, have more than 2,200 staffed beds. The hospital and physician members of SGHP as a group provide services in a very large section of south Georgia, extending eastward in Georgia from the Alabama border through Ware County and including the cities of Valdosta, Tifton, Thomasville, Moultrie, and Waycross ("South Georgia"). The area has a population of approximately 550,000. Approximately 90% of all physicians practicing in South Georgia are SGHP members, and

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SGHP's 15 hospital members are the sole hospitals (with the exception of one small hospital in Valdosta) in the mostly contiguous counties in which they are located.

THE OWNER PHO RESPONDENTS

6. Coastal Plains Health Alliance is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 160 East Second Street, Tifton, Georgia 31794. Coastal Plains Health Alliance is a PHO that jointly owns SGHP with the other Owner PHOs. Tift Regional Medical Center, and approximately 90% of all physicians in Tift County, are its members.

7. Colquitt County PHO is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 2421 South Main Street, Moultrie, Georgia 31768. It is a PHO that jointly owns SGHP with the other Owner PHOs. Colquitt Regional Medical Center, and approximately 90% of all physicians in Colquitt County, are its members.

8. Health Alliance of the South is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is John D. Archbold Memorial Hospital, 915 Gordon Avenue, Thomasville, Georgia 31792. Health Alliance of the South is a PHO that jointly owns SGHP with the other Owner PHOs. Its hospital members are John D. Archbold Memorial Hospital in Thomasville, and four hospitals leased and managed by John D. Archbold Memorial Hospital: Brooks County Hospital in Quitman; Early Memorial Hospital in Blakely; Grady General Hospital in Cairo; and Mitchell County Hospital in Camilla. Approximately 90% of all physicians in Thomas County, and a high percentage of the physicians in the counties of Brooks, Early, Grady, and Mitchell, are also members of Health Alliance of the South.

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9. Satilla HealthNet is a non-profit corporation that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 1800 Alice Street, Waycross, Georgia 31501. Satilla HealthNet is a PHO that jointly owns SGHP with the other Owner PHOs. Satilla Regional Medical Center, and approximately 90% of all physicians in Ware County, are its members.

10. South Georgia PHO is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 2501 North Patterson Street, Valdosta, Georgia 31602. It is a PHO that jointly owns SGHP with the other Owner PHOs. South Georgia Medical Center in Valdosta and Louis Smith Memorial Hospital in Lakeland, a hospital leased and managed by South Georgia Medical Center, along with approximately 90% of all physicians in Lowndes and Lanier counties, are members of South Georgia PHO.

THE IPA RESPONDENTS

11. Colquitt County Physicians is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 2421 South Main Street, Moultrie, Georgia 31768. Colquitt County Physicians is an IPA that includes approximately 90% of all physicians in Colquitt County, and is itself affiliated with Colquitt County PHO.

12. Qualicare Physicians Association is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 808 Gordon Avenue, Thomasville, Georgia 31792. Qualicare Physicians Association is an IPA that includes approximately 90% of all physicians in Thomas County, and is itself affiliated with Health Alliance of the South.

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13. South Georgia Physician Network is a for-profit limited liability company that is organized, existing, and doing business under, and by virtue of, the laws of the State of Georgia. Its principal address is 102 W. Moore Street, Valdosta, Georgia 31602. South Georgia Physician Network is an IPA that includes approximately 90% of all physicians in Lowndes County, and is itself affiliated with South Georgia PHO.

JURISDICTION

14. Respondents' general business practices and conduct, including the acts, practices, and conduct alleged herein, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

15. Respondent Satilla HealthNet is organized in substantial part, and is engaged in substantial activities, for its members' pecuniary benefit, and therefore is a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

OVERVIEW OF PHYSICIAN AND HOSPITAL CONTRACTING WITH PAYORS

16. Physicians, hospitals, PHOs, and IPAs often enter into contracts with payors that establish the terms and conditions, including prices and other competitively significant terms, upon which such health care providers will provide professional services to subscribers of the payors' health care plans. Physicians, hospitals, PHOs, and IPAs contracting with payors often agree to reductions in their compensation to obtain access to additional patients made available by the payors' relationship with their health plan enrollees. These contracts may reduce payors' costs, enable them to lower the price of health insurance, and reduce out-of-pocket medical care expenditures by subscribers to the payors' health insurance plans.

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17. Physicians organize their practices under several models, including, but not limited to, sole proprietorships, partnerships, and professional corporations (collectively “physician entities”). Absent agreements among them on the terms on which they will provide services to payors’ health plan enrollees, competing physician entities decide unilaterally whether to enter into contracts with payors to provide services to the payor’s enrollees, and at what prices and upon what other terms and conditions they will accept such contracts.

18. Likewise, absent agreements among them on the terms on which they will provide services to payors’ health plan enrollees, competing hospitals decide unilaterally whether to enter into contracts with payors to provide hospital services to the payor’s enrollees, and at what prices and upon what other terms and conditions they will accept such contracts.

19. Physicians sometimes participate in IPAs that enter into contracts with payors for the provision of physician services. An IPA may involve integration among its participating physicians in ways that create efficiencies sufficient to justify the IPA’s negotiation and execution of payor contracts on its physicians’ collective behalf. For example, in some IPAs, physicians share with each other the risk that the total costs of member physician services to a payor’s health plan enrollees may exceed targeted levels. Such physicians usually agree to follow guidelines relating to quality assurance, utilization review, administrative efficiency, and other components of cost, to improve efficiency and minimize this risk of financial loss. Agreement among such financial risk-sharing IPA members on the price to charge for the provision of their services may be reasonably necessary to achieve these efficiencies.

20. Absent agreements with non-member physicians on the terms on which they will provide services to payors’ health plan enrollees, integrated IPAs decide unilaterally whether to enter into contracts with payors to provide physician services to the payor’s

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enrollees, and at what prices and upon what other terms and conditions they will accept such contracts.

21. Physicians and hospitals sometimes participate in PHOs that enter into contracts with payors for the provision of physician and hospital services. A PHO may involve integration among its participating physicians and hospitals (if more than one hospital participates) in ways that create efficiencies sufficient to justify the PHO's negotiation and execution of payor contracts on its physicians' and hospitals' collective behalf. For example, in some PHOs, physician members share with each other the risk that the total costs of physician services to a payor's health plan enrollees may exceed targeted levels. Such physicians usually agree to follow guidelines relating to quality assurance, utilization review, administrative efficiency, and other components of cost, to improve efficiency and minimize this risk of financial loss. Agreement among such financial risk-sharing PHO members on the price to charge for the provision of their services may be reasonably necessary to achieve these efficiencies.

22. Medicare's Resource Based Relative Value Scale ("RBRVS") is a system used by the United States Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services, and to compare fees. In general, payors in South Georgia contract with individual physicians or groups at a price level specified as some percentage of the RBRVS fee for a particular year (*e.g.*, "120% of 2003 RBRVS"), or, for their own analysis, they sometimes calculate the percentage of RBRVS that a physician's price list would equal.

23. Contracts between payors and hospitals contain various methods for determining prices for inpatient services. One such method is a "per diem" payment, which is a set charge per day for a particular inpatient service. Another method is "per case rate." This is a set charge for a particular type of case, which often is defined by the applicable "diagnosis related group" (or "DRG").

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Per diem and per case rate methods can make pricing more certain and provide incentives for hospitals to use resources more efficiently. A third method is a set percentage discount off the hospital's list prices. This method often does not prevent the hospital, during the contract period, from unilaterally raising the list prices to which the discount is applied.

**RESPONDENTS ARE ORGANIZATIONS OF
COMPETITORS**

24. At all times relevant to this Complaint, the physician members of SGHP, the Owner PHOs, and the IPA Respondents were engaged in the business of providing physician services for a fee. Except to the extent that competition has been restrained as alleged herein, physician members of each Respondent have been, and are now, in competition with each other, and with physician members of other Respondents, for the provision of physician services.

25. At all times relevant to this Complaint, the hospital members of SGHP and the Owner PHOs were engaged in the business of providing hospital services for a fee. Except to the extent that competition has been restrained as alleged herein, hospital members of such Respondents have been, and are now, in competition with each other for the provision of hospital services.

26. To be competitive in South Georgia, a payor's health insurance plan must include in its provider networks at least one of the SGHP member hospitals and a large number of the physicians who practice in that region. In any given area of South Georgia, approximately 90% of the practicing physicians are members of SGHP.

SGHP'S FORMATION AND OPERATION

27. In 1995, four Owner PHOs – Coastal Plains Health Alliance, Colquitt County PHO, Health Alliance of the South, and South Georgia PHO – formed SGHP, each taking a 25%

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ownership share. They agreed that SGHP would become a vehicle through which their member hospitals and member physicians would negotiate collectively for payor contracts. A Colquitt County PHO executive explained that SGHP “would in essence keep the [member] hospitals from competing . . . and ending up with a price war that would not benefit any of the major hospitals,” and would look “to reimburse the physicians a professional rate as high as the market will bear.”

28. In 2001, Satilla HealthNet became SGHP’s fifth Owner PHO, and the five Owner PHOs each took 20% ownership shares. Satilla HealthNet’s chief executive explained its joining SGHP as “an opportunity to improve our presence or ‘clout’ while negotiating contracts” with payors.

29. SGHP has a 20-member board of directors. Each Owner PHO appoints four board members – two physicians and two hospital representatives. An IPA Respondent selects the physician board members for the slots belonging to the Owner PHO with which it is affiliated. To join SGHP, a physician must belong to an Owner PHO and pay annual dues to SGHP. Virtually every physician member of an Owner PHO and an IPA Respondent is also a dues-paying member of SGHP.

30. According to SGHP’s records: “It is the policy of South Georgia Health Partners that all statewide and national managed care contracting be conducted through the Contract Review Committee who will engage in the evaluation and negotiation of managed care contracts in accordance with the criteria set forth by the South Georgia Health Partners Board of Directors. South Georgia Health Partners Board of Directors will have final approval of all managed care contracts recommended by the Contract Review Committee.” The chief executive and chief financial officers of the flagship hospital members of the Owner PHOs, along with physician representatives, constitute the Contract Review Committee.

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31. After forming SGHP, the Owner PHOs, member hospitals, and member physicians began to cancel contracts with payors and to inform them that SGHP was the sole entity through which they would enter into future payor contracts. Thereafter, SGHP began to negotiate fee-for-service contracts with payors on behalf of its physician and hospital members. Members bill payors directly for services rendered, and payors remit payment directly to the physicians and hospitals. SGHP has not entered into any payor contracts that did not include both hospital and physician members. As an SGHP executive stated in a July 1997 board of directors meeting concerning a particular payor contract, "we want to include the physician component in this contract, not just negotiate on behalf of the hospitals but negotiate on behalf of South Georgia Health Partners as one entity."

SGHP Physician Contracting Practices

32. SGHP has a single price list for its member physicians. Payors must agree to pay the prices on SGHP's price list or forfeit the ability to enter into an SGHP contract for physician services. Payors have tried, but failed, to negotiate with SGHP for price reductions from this list. On a weighted average, SGHP's physician prices are approximately 187% of RBRVS, which is a substantially higher rate than payors pay elsewhere in Georgia.

33. SGHP's rules do not prohibit member physicians from contracting with payors separately from SGHP, and permit member physicians to choose whether to "opt in" or "opt out" of payor contracts that SGHP negotiates. In practice, however, SGHP physicians regularly insist on dealing with payors only pursuant to an SGHP contract, to maximize the negotiating leverage that results from acting in concert with their competitors. For example, at a 1997 board meeting, SGHP directors agreed to send a letter to physician members, warning them that they should not participate in a health plan that offered insufficient payment terms.

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34. The practice of, and rationale for, physician collective action through SGHP is reflected in messages that SGHP leaders repeatedly conveyed to the membership. For example, at the same July 1997 board meeting, an SGHP board member asserted that “if you announce to 350 physicians in South Georgia ‘don’t sign [a certain contract]’ and hopefully get good participation in not signing it, [the payor] will go away with this fee schedule . . . and have to come back with something more competitive.” Similarly, at a meeting in 2000, a leader of IPA Respondent South Georgia Physician Network told other physician members: “**Stay together, if nothing else stay together!** [Emphasis in original.] Strong physician groups are powerful organizations. . . . There will be unprecedented efforts to create fissures in the organization and bring about [two] competitive IPAs that can be played against one another.”

SGHP Hospital Contracting Practices

35. SGHP negotiates payor contracts, including price terms, on its member hospitals’ collective behalf. Member hospitals determine their own respective price lists and submit them to SGHP negotiators. SGHP, in turn, through the authority vested in it by the board of directors, fixes the maximum allowable percentage discount from member hospital price lists. SGHP has fixed the discount at a level not to exceed 10%, and has refused repeated payor requests for deeper discounts for particular, and for all, member hospitals. SGHP has also successfully resisted payor attempts to negotiate changes in hospital list prices, or to obtain hospital pricing on a per diem or per case basis.

36. SGHP member hospitals have agreed, and memorialized into the SGHP operating agreement, that they will not deal independently of SGHP for most payor contracts, unless 75% of the SGHP board votes to authorize an exception to this practice. The board enforces this requirement. For example, in 2001, the City of Valdosta, Georgia, which insures its employees, desired to contract separately with South Georgia Medical Center, an SGHP member and Owner PHO member. SGHP’s contract review

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committee “did not feel that allowing [the hospital] to contract independently with the City of Valdosta was wise” and recommended that the board forbid the hospital from doing so. On June 25, 2001, the board voted unanimously to forbid the contract.

37. The SGHP hospitals have agreed that even if an SGHP member hospital is authorized by the SGHP board to contract independently with a payor, that hospital cannot provide a discount from its respective list prices greater than 10%, unless that hospital agrees to provide the deeper discount to every payor with which SGHP has a contract. Members have referred to this as SGHP’s “most-favored-nations” clause. This agreement creates a substantial disincentive for any member hospital to deviate from the 10% discount level, because, by lowering prices to one payor, the hospital would have to do so for all payors with which it was under contract. For example, in negotiations with one payor, at least one SGHP hospital member would have accepted a proposed 15% discount from list prices, but ultimately refrained from doing so because – under the most-favored-nations requirement in its SGHP agreement – the hospital would have had to extend this price savings to all other payors with which it had a contract.

38. The most-favored-nations clause served SGHP hospital members’ collusive purposes, therefore, by creating a substantial disincentive for any member hospital to offer a discount greater than the organization’s fixed 10% discount. In practice, hospitals have not deviated from this fixed discount maximum – resulting in substantially higher prices to payors. To enforce this requirement as to the five member hospitals not belonging to an Owner PHO, moreover, SGHP can demand that the hospital certify that it is not providing more favorable pricing terms to any payor, and may audit the hospital’s prices to assess the accuracy of the certification.

39. The SGHP hospitals have also agreed that all of them must perform under any payor contract that SGHP enters, unless 75%

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of the SGHP board votes to authorize an exception. SGHP has also required payors to agree to an exclusivity clause in their contracts with SGHP, under which the payor is not allowed to cover services at any non-SGHP hospital in South Georgia. This has blocked some payors' ability to access the services at Smith Hospital in Valdosta, which is not a member of SGHP.

40. In addition to maintaining artificially high prices by concertedly fixing the rate of discounts from list prices, SGHP's restrictive contracting practices for hospitals prevent payors from selecting particular hospitals with which to negotiate for inclusion in the payors' health plan networks. Absent SGHP's policies, in negotiating with selected hospitals, payors would offer access to their subscriber base in exchange for significant reduction in hospital prices.

**RESPONDENTS' ANTICOMPETITIVE ACTS AND
PRACTICES IN DEALING WITH PARTICULAR PAYORS**

UnitedHealth Group

41. UnitedHealth Group is a payor doing business in South Georgia. In 2001, United attempted to negotiate individual contracts with physician and hospital members of SGHP. The SGHP members refused to negotiate unilaterally, however, and consistently referred United to SGHP as their bargaining entity. Having no reasonable alternative but to follow the physicians' and hospitals' instructions, United attempted to bargain with SGHP – offering to pay for physician services at 140% of 2001 RBRVS and for hospital services at list prices minus a 25% discount. SGHP rejected United's offer. It demanded that United pay for physician services according to SGHP's price list (approximately 187% of RBRVS, on a weighted average basis) and for hospital services according to each member hospital's price list, minus a 10% discount. To be in a position to market a health care plan in South Georgia, United had no choice but to meet SGHP's price terms, and did so.

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Coventry Health Care

42. Coventry Health Care assembles networks of physicians and hospitals and, for a fee, offers those networks to payors for inclusion in their health care plans. In 1999, one of SGHP's Owner PHOs, South Georgia PHO, terminated its relationship with Coventry, and told Coventry that its physician and hospital services would be available only as part of an agreement with SGHP. In contract negotiations, SGHP demanded that Coventry contract exclusively with SGHP member physicians and pay them according to SGHP's price list, which on average meant a 40% price increase to Coventry. SGHP also insisted that Coventry pay higher prices to South Georgia Medical Center by accepting a discount off list prices that was smaller, by about one-third, than Coventry's then-existing discount.

43. Faced with SGHP's demands for higher hospital and physician prices, Coventry attempted to deal individually with SGHP member hospitals and physicians to obtain lower prices. Coventry consistently was unsuccessful in this effort. SGHP members told Coventry that it must deal with SGHP to obtain its members' services. Having no reasonable alternatives in South Georgia, Coventry met SGHP's terms and signed a contract. The prices that Coventry is paying for physician services under its SGHP contract are the highest that Coventry pays in Georgia.

South Georgia Purchasing Alliance

44. South Georgia Purchasing Alliance ("Alliance") is a coalition of 20 of the larger employers in South Georgia, most of which are located in or near Valdosta, Georgia. In 2002, the Alliance attempted to purchase health insurance for its members' employees, and reached a tentative agreement on a contract with South Georgia Medical Center, which is a member of SGHP. SGHP's board of directors voted to reject the contract, however, and to prohibit South Georgia Medical Center from dealing individually with the Alliance.

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45. During 2001 and 2002, the Alliance also attempted to contract for physician services through SGHP, South Georgia PHO, and South Georgia Physician Network. The Alliance offered to pay the physicians, on a weighted average basis, approximately 150% of the current year's RBRVS. All of the physician groups rejected the Alliance's offer, however, and insisted that the Alliance meet SGHP's physician fee schedule, which, on a weighted average basis, equaled approximately 187% of RBRVS. Over the same period, the Alliance attempted to contract on an individual basis with more than 160 Valdosta-based physicians. Only six of them agreed to contract with the Alliance. As a result of SGHP's restrictive policies, the Alliance is blocked from assembling a health plan network for the employees of its member companies.

Cigna Health Care

46. Cigna Health Care is a payor doing business in South Georgia. In 2002, SGHP member hospitals terminated their participation in the lowest-priced health plan that Cigna offered to employers in South Georgia. Thereafter, Cigna contacted each hospital on an individual basis and attempted to negotiate new contract terms with each of them. The hospitals refused to negotiate unilaterally and told Cigna that it would have to bargain with SGHP for their services under this plan. Having no reasonable alternative but to follow the hospitals' instructions, Cigna attempted to bargain with SGHP, which told Cigna that it negotiated on the collective behalf of all SGHP member hospitals and physicians.

47. SGHP told Cigna that, to obtain a contract for services from SGHP's hospital members, Cigna must pay what would have amounted to approximately an 80% increase in the prices that Cigna had been paying to SGHP hospitals under this plan. SGHP also insisted that Cigna pay its physicians according to SGHP's physician services price list, which contained, on average, the highest prices in Georgia. SGHP's price demands were too costly for Cigna to continue marketing its low-cost health plan to

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employers; consequently, it stopped selling the plan in South Georgia. As a result, employers were compelled to purchase a higher-priced, alternative health plan, or to discontinue their provision of health insurance to their employees.

Other Payors

48. Respondents have orchestrated collective negotiations with other payors that do business, or attempted to do business, in South Georgia, including Blue Cross and Blue Shield of Georgia, NovaNet, One Health Plan of Georgia, Beech Street Corporation, and Private Health Care Systems. Respondents, through and with SGHP, fixed price terms for physician and hospital services and refused to enter contracts with payors that would not meet those terms. Due to SGHP's dominant market position in South Georgia, its tactics have been highly successful. SGHP member physicians and hospitals have been able to extract far higher prices from these payors than they could have obtained by negotiating unilaterally.

**RESPONDENTS HAVE ENGAGED IN RESTRAINTS
OF TRADE**

49. Respondents, acting as a combination of competing physicians and hospitals, have restrained competition by, among other things:

- A. facilitating, negotiating, entering into, and implementing agreements on price and other competitively significant terms;
- B. refusing to deal with payors except on collectively agreed-upon terms; and
- C. negotiating prices and other competitively significant terms in contracts with payors.

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**NO SIGNIFICANT EFFICIENCIES JUSTIFY
RESPONDENTS' CONDUCT**

50. Respondents' joint negotiation of prices and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration sufficient to justify the acts and practices described above.

ANTICOMPETITIVE EFFECTS

51. Respondents' actions described in paragraphs 1 and 27 through 49 of this Complaint have had, or have tended to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician and hospital services in South Georgia in the following ways, among others:

- A. price and other forms of competition among Respondents' physician members were unreasonably restrained;
- B. price and other forms of competition among Respondents' hospital members were unreasonably restrained;
- C. prices for physician services were increased;
- D. prices for hospital services were increased;
- E. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians;
- F. health plans, employers, and individual consumers were deprived of the benefits of competition among hospitals.

52. The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, conspiracy, acts and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

Complaint

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirty-first day of October, 2003, issues its Complaint.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of South Georgia Health Partners, L.L.C. (“SGHP”); Coastal Plains Health Alliance, L.L.C. (“Coastal Plains Health Alliance”); Colquitt County PHO, L.L.C. (“Colquitt County PHO”); Colquitt County Physicians Association, L.L.C. (“Colquitt County Physicians”); Georgia/Florida Preferred, L.L.C., dba Health Alliance of the South (“Health Alliance of the South”); Qualicare Physicians Association, L.L.C. (“Qualicare Physicians Association”); Satilla HealthNet, Inc. (“Satilla HealthNet”); South Georgia PHO, L.L.C. (“South Georgia PHO”); and South Georgia Physician Network, L.L.C. (“South Georgia Physician Network”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of the draft of Complaint that counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the

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public record for a period of thirty (30) days for the receipt and consideration of public comments, and having carefully considered the comments received from interested persons, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order:

1. Respondent SGHP is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 160 East Second Street, Tifton, Georgia 31794.
2. Respondent Coastal Plains Health Alliance is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 160 East Second Street, Tifton, Georgia 31794.
3. Respondent Colquitt County PHO is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 2421 South Main Street, Moultrie, Georgia 31768.
4. Respondent Colquitt County Physicians is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 2421 South Main Street, Moultrie, Georgia 31768.
5. Respondent Health Alliance of the South is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business

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located at John D. Archbold Memorial Hospital, 915
Gordon Avenue, Thomasville, Georgia 31792.

6. Respondent Qualicare Physicians Association is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 808 Gordon Avenue, Thomasville, Georgia 31792.
7. Respondent Satilla HealthNet is a non-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 1800 Alice Street, Waycross, Georgia 31501.
8. Respondent South Georgia PHO is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 2501 North Patterson Street, Valdosta, Georgia 31602.
9. Respondent South Georgia Physician Network is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Georgia, with its office and principal place of business located at 102 W. Moore Street, Valdosta, Georgia 31602.
10. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

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- A. “Respondent SGHP” means South Georgia Health Partners, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. “Respondent Coastal Plains Health Alliance” means Coastal Plains Health Alliance, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- C. “Respondent Colquitt County PHO” means Colquitt County PHO, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- D. “Respondent Colquitt County Physicians” means Colquitt County Physicians Association, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- E. “Respondent Health Alliance of the South” means Georgia/Florida Preferred, L.L.C., dba Health Alliance of the South, its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.

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- F. “Respondent Qualicare Physicians Association” means Qualicare Physicians Association, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- G. “Respondent Satilla HealthNet” means Satilla HealthNet, Inc., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- H. “Respondent South Georgia PHO” means South Georgia PHO, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- I. “Respondent South Georgia Physician Network” means South Georgia Physician Network, L.L.C., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- J. “Hospital” means a health care facility that provides inpatient and outpatient care and services for the diagnosis and treatment of medical conditions.
- K. “Hospital system” means an organization comprising two or more hospitals where the same person(s) controls each hospital in the organization. For purposes of this

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definition, the definition of the term “control” under 16 C.F.R. § 801.1(b) shall apply. “Hospital system” includes a hospital that is managed under contract, or is leased, by a hospital member of a Respondent Owner PHO.

- L. “Respondent IPAs” means Respondents Colquitt County Physicians, Qualicare Physicians Association, and South Georgia Physician Network. “Respondent Owner PHOs” means Respondents Coastal Plains Health Alliance, Colquitt County PHO, Health Alliance of the South, Satilla HealthNet, and South Georgia PHO.
- M. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services to a payor through such entity. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- N. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician or hospital services for itself or for any other person. Payor includes any person that develops, leases, or sells access to networks of physicians or hospitals.
- O. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- P. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- Q. “Preexisting contract” means a contract that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by a Respondent, pursuant to Paragraph V.A.3. or Paragraph V.A.4. of this Order, of such payor’s right to terminate such contract.

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- R. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- S. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services, hospital services, or both physician and hospital services in which:
1. All physicians and hospitals that participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians and hospitals that participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 2. Any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.
- U. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services, hospital services, or both physician and hospital services in which:
1. All physicians and hospitals that participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians and hospitals that participate to jointly control costs and improve quality by managing the provision of physician and hospital services, such as risk-sharing involving:
 - a. the provision of physician or hospital services to payors at a capitated rate;

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- b. the provision of physician or hospital services for a predetermined percentage of premium or revenue from payors;
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians or hospitals that participate to achieve, as a group, specified cost-containment goals; or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by hospitals or physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
2. Any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.

II.

IT IS FURTHER ORDERED that each Respondent, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:

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1. To negotiate on behalf of any physician with any payor;
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent(s);
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal with a payor;
- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B. above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED, HOWEVER, that, nothing in this Paragraph II. shall prohibit any agreement involving, or conduct by any Respondent Owner PHO or any Respondent IPA, subject to the provisions of Paragraph IV. below, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement, so long as the arrangement does not include more than one Respondent Owner PHO or more than one Respondent IPA, and so long as the arrangement does not restrict the ability,

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or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement.

III.

IT IS FURTHER ORDERED that each Respondent, directly or indirectly, or through any corporate or other device, in connection with the provision of hospital services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any hospitals:
 - 1. To negotiate on behalf of any hospital with any payor;
 - 2. To deal, refuse to deal, or threaten to refuse to deal with any payor;
 - 3. Regarding any term, condition, or requirement upon which any hospital deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 - 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent(s);
- B. Exchanging or facilitating in any manner the exchange or transfer of information between or among hospitals concerning any hospital’s willingness to deal with a payor, or the terms or conditions, including price terms, on which the hospital is willing to deal with a payor;
- C. Attempting to engage in any action prohibited by Paragraph III.A. or III.B. above; and

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- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs III.A. through III.C. above.

PROVIDED, HOWEVER, that, nothing in this Paragraph III. shall prohibit any agreement involving, or conduct by any Respondent Owner PHO or any Respondent IPA, subject to the provisions of Paragraph IV. below, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement, or that solely involves hospitals in the same hospital system, so long as the arrangement does not include more than one Respondent Owner PHO or more than one Respondent IPA, and so long as the arrangement does not restrict the ability, or facilitate the refusal, of hospitals that participate in it to deal with payors on an individual basis or through any other arrangement.

IV.

IT IS FURTHER ORDERED that:

- A. Each Respondent Owner PHO and each Respondent IPA that has formed a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement (“Arrangement”) shall, for five (5) years from the date this Order becomes final, notify the Secretary of the Commission in writing (“Notification”) at least sixty (60) days prior to:
1. Participating in, organizing, or facilitating any discussion or understanding with or among any physicians or hospitals in such Arrangement relating to price or other terms or conditions of dealing with any payor; or

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2. Contacting a payor, pursuant to an Arrangement to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any payor, on behalf of any physician or hospital in such Arrangement. Notification is not required for contacts with subsequent payors pursuant to any Arrangement for which this Notification was given;
- B. With respect to any Arrangement, each Respondent Owner PHO and each Respondent IPA shall include the following information in the Notification:
1. For each physician participant, his or her name, address, telephone number, medical specialty, medical practice group, if applicable, and the name of each hospital where he or she has privileges;
 2. For each hospital participant, the hospital name and the name and telephone number of the person responsible for that hospital participant's relationship with that Respondent;
 3. A description of the Arrangement and its purpose, function, and geographic area of operation;
 4. A description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;
 5. An explanation of how any agreement on prices (or on contract terms related to price) furthers the integration and achieves the efficiencies of the Arrangement;
 6. A description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities; and
 7. All studies, analyses, and reports that were prepared for the purpose of evaluating or analyzing competition for

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physician or hospital services in any relevant market, including, but not limited to, the market share of physician services in any relevant market or the market share of hospital services in any relevant market;

- C. If, within sixty (60) days from the Commission's receipt of the Notification, a representative of the Commission makes a written request for additional information to a Respondent Owner PHO or to a Respondent IPA, that Respondent Owner PHO or Respondent IPA shall not engage in any conduct described in Paragraph IV.A. prior to the expiration of thirty (30) days after substantially complying with such request for additional information, or such shorter waiting period as may be granted in writing from the Bureau of Competition. The expiration of any waiting period described herein without a request for additional information or without the initiation of an enforcement proceeding shall not be construed as a determination by the Commission, or its staff, that a violation of the law, or of this Order, may not have occurred. Further, receipt by the Commission from a Respondent Owner PHO or a Respondent IPA of any Notification of an Arrangement is not to be construed as a determination by the Commission that any such Arrangement does or does not violate this Order or any law enforced by the Commission, including, but not limited to, Sections 7 and 7A of the Clayton Act, 15 U.S.C. §§ 18 and 18a.

V.

IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date on which this Order becomes final:

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1. Respondent SGHP shall send by first-class mail, with delivery confirmation, a copy of this Order and the Complaint to:
 - a. each physician and hospital that participates or has participated in Respondent SGHP; and
 - b. each officer, director, manager, and employee of Respondent SGHP;
2. Each Respondent Owner PHO shall send by first-class mail, with delivery confirmation, a copy of this Order and the Complaint to:
 - a. each physician and hospital that participates or has participated in that Respondent Owner PHO and has not been sent this required notice by Respondent SGHP; and
 - b. each officer, director, manager, and employee of that Respondent Owner PHO;
3. Respondent SGHP shall send by first-class mail, return receipt requested, copies of this Order, the Complaint, and the notice specified in Appendix A to this Order to the chief executive officer of each payor with which the Respondent SGHP has a record of having been in contact since January 1, 1995, regarding contracting for the provision of physician or hospital services;
4. Each Respondent Owner PHO shall send by first-class mail, return receipt requested, copies of this Order, the Complaint, and the notice specified in Appendix A to this Order to the chief executive officer of each payor with which the Respondent Owner PHO has a record of having been in contact since January 1, 1995, regarding

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contracting for the provision of physician or hospital services and that has not been sent this required notice from Respondent SGHP;

- B. Each Respondent having a preexisting contract with any payor for the provision of physician or hospital services shall terminate, without penalty or charge, and in compliance with any applicable laws of the State of Georgia, that preexisting contract at the earlier of: (1) the termination or renewal date (including any automatic renewal date) of such contract; or (2) receipt by Respondent of a written request to terminate such contract from any payor that is a party to the preexisting contract;
- C. For three (3) years from the date this Order becomes final, each Respondent shall:
 - 1. Distribute by first-class mail, return receipt requested, a copy of this Order and the Complaint to:
 - a. each physician or hospital that begins participating in Respondent and did not previously receive a copy of this Order and the Complaint, within thirty (30) days of the time that such participation begins;
 - b. each payor that contracts with such Respondent for the provision of physician or hospital services and did not previously receive a copy of this Order and the Complaint, within thirty (30) days of the time that such payor enters into such contract;
 - c. each person who becomes an officer, director, manager, or employee of such Respondent and did not previously receive a copy of this Order and the Complaint, within thirty (30) days of the time that he or she assumes such responsibility with such Respondent; and

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2. Annually publish a copy of this Order and the Complaint in an official report or newsletter sent to all physicians and hospitals that participate in any Respondent, with such prominence as is given to regularly featured articles;
- D. Each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in such Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries, or any other change in such Respondent that may affect compliance obligations arising out of this Order; and
- E. Each Respondent shall file verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include:
1. A detailed description of the manner and form in which such Respondent has complied and is complying with this Order;
 2. The name, address, and telephone number of each payor with which such Respondent has had any contact; and
 3. Copies of the signed return receipts and delivery confirmation required by this Paragraph V.

VI.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its respective principal address within twenty (20) days of such change in address.

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VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondent, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate on October 31, 2023.

By the Commission, Commissioner Harbour not participating.

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Appendix A

[letterhead of Respondent sending letter]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against South Georgia Health Partners (SGHP) and eight other organizations.

Pursuant to Paragraph V.B. of the order, you have the immediate right, upon written request, to terminate any contracts with SGHP or the other organizations subject to this order that were in effect prior to the receipt of this letter, without penalty or charge. In accordance with Paragraph V.B., any contract that you do not thus terminate will end at its termination or renewal date (including any automatic renewal date).

Sincerely,

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with South Georgia Health Partners, L.L.C. (“SGHP”), five other physician-hospital organizations (“PHOs”), and three independent practice associations (“IPAs”). The agreement settles charges that these nine respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among SGHP’s members to fix prices and other terms of dealing with employers, health insurance firms, and other third-party payors (“payors”) for physician and hospital services, and to refuse to deal with payors except on collectively determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any respondent that said respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint Allegations

According to the Commission’s complaint, SGHP is a for-profit PHO, the membership of which includes competing hospitals and competing physicians. All its members are located in a region of south Georgia. Through SGHP, the members bargain collectively for higher prices for hospital and physician

Analysis

services. SGHP consists of approximately 500 physicians, as well as 15 hospitals with a total of over 2,200 staffed beds. With one exception, SGHP's member hospitals are the sole hospitals in each of the 15 counties where they are located. SGHP's member physicians constitute approximately 90% of all physicians who practice in the area.

Five respondents – each itself a PHO (the “Owner PHOs”) – own equal shares of SGHP: Health Alliance of the South, South Georgia PHO, Coastal Plains Health Alliance, Colquitt County PHO, and Satilla HealthNet. Each has equal representation on SGHP's Board of Directors. The three IPA respondents – Qualicare Physicians Association, South Georgia Physician Network, and Colquitt County Physicians – are the physician components of three of the owner PHOs. The complaint alleges that these eight respondents, with and through SGHP, agreed to fix physician and hospital prices.

Physicians sometimes join IPAs, and physicians and hospitals sometimes form PHOs, to market jointly their health care services to payors or engage in other collective activities. Such organizations may not lawfully orchestrate agreements among their members on the prices to demand from payors, unless the members are integrated in a manner that creates significant efficiencies such as lower costs, and unless the price agreements are reasonably necessary to obtain those efficiencies. According to the complaint, neither SGHP, nor any other respondent, engaged in such integration so as to justify their price-fixing activities.

The complaint further alleges that, with respect to physician services, SGHP required payors to meet a single, fixed price list applicable to all physician members. The prices that SGHP demanded are substantially higher than the physicians could have obtained by negotiating unilaterally. When payors approached them directly in efforts to engage in contract negotiations, SGHP's physician members repeatedly refused to deal unilaterally, and

Analysis

instructed the payors to negotiate with SGHP for collective contracting purposes.

With respect to hospital services, the complaint alleges that SGHP orchestrated agreements among its hospital members not to discount from their respective list prices by an amount greater than 10%, and repeatedly refused payor requests during contract negotiations for larger discounts for specific SGHP member hospitals or combinations of member hospitals. SGHP successfully resisted payor attempts to contract separately with individual member hospitals. It also fostered agreements among its members to refuse payor requests for hospital services payable on the basis of a per diem (set charge per day for a particular inpatient service) or per case (set charge for a particular type of case, including “diagnosis related groups” or “DRGs”). These are methods that can make pricing more certain and provide incentives for hospitals to use resources more efficiently.

SGHP also allegedly orchestrated agreements among its member hospitals to participate only in SGHP’s contract arrangements with payors. A hospital that wanted to deal with a payor outside of SGHP needed authorization from 75% of SGHP’s board to do so. SGHP further required that, if the board authorized a member hospital to contract independently from SGHP, the hospital not discount from its list prices by more than 10% – unless the hospital provided that larger discount to every payor with which it was under contract through SGHP. This agreement created a substantial disincentive for any member hospital to deviate from the SGHP price agreement, because, by lowering prices to one payor, the hospital would have to do so for all payors that had contracts with the hospital.

Eight of the nine respondents are for-profit entities. The other respondent, Satilla HealthNet, is a non-profit corporation, but one that engages in substantial activities that confer pecuniary benefits on its for-profit physician members. The Commission has jurisdiction, therefore, over all respondents.

Analysis

The Proposed Consent Order

The proposed order is designed to remedy the illegal conduct charged in the complaint and prevent its recurrence, while allowing respondents to engage in legitimate conduct that does not impair competition. It is similar to many previous consent orders that the Commission has issued to settle charges relating to unlawful agreements to raise prices. The proposed order applies to both hospital and physician services.

The proposed order's specific provisions are as follows:

The proposed order's core prohibitions are contained in Paragraphs II and III. Paragraph II.A prohibits respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten to refuse to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than respondents.

Paragraph II.B prohibits respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bans them from attempting to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D prohibits them from inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

Paragraph II also contains a proviso intended to clarify certain types of agreements that Paragraph II does not prohibit, except as to SGHP. It provides that nothing in Paragraph II prohibits the Owner PHO and IPA respondents from engaging in conduct that is reasonably necessary to form, participate in, or act in furtherance of, a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement." Such arrangements must not include another Owner PHO or IPA, and they must not be exclusive. As discussed below in connection

Analysis

with Paragraph IV, each respondent is required to notify the FTC about such an arrangement before negotiating on behalf of its members or before its members jointly discuss any terms of dealing with a payor.

As defined in the proposed order, a “qualified risk-sharing joint arrangement” must satisfy two conditions. First, all physician or hospital participants must share substantial financial risk through the arrangement and thereby create incentives for the physician or hospital participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

As defined in the proposed order, a “qualified clinically-integrated joint arrangement” also must satisfy two conditions. First, all physician or hospital participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among physicians and/or hospitals, in order to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

Paragraph III is substantially identical to Paragraph II, except that it applies to the provision of hospital, rather than physician, services.

Paragraph IV requires an Owner PHO or IPA respondent that has formed a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement to notify the Commission at least 60 days prior to negotiating or entering into agreements with payors, or discussing price or related terms among the participants of the arrangement. Paragraph IV.B sets out the information necessary to make the notification complete.

Analysis

Paragraph IV.C establishes the Commission's right to obtain additional information regarding the arrangement.

Paragraphs V.A, V.B, and V.C set out the requirement that SGHP or Owner PHO respondents send the Order, the Complaint, and a letter of notice to each payor with which SGHP or an Owner PHO has been in contact since January 1, 1995. This notice provision, set out in Appendix A, will inform payors that any contract with SGHP may be terminated at the payor's written request, per Paragraph V.B. Absent such written request, however, Paragraph V.B provides that all such contracts will terminate upon their termination or renewal date. This provision is intended to eliminate the effects of respondents' anticompetitive concerted actions. The remaining provisions of Paragraph V and Paragraphs VI through VIII of the proposed order impose obligations on respondents with respect to distributing the proposed complaint and order to SGHP's members and to other specified persons, and reporting information to the Commission.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

NESTLÉ HOLDINGS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

*Docket C-4082; File No. 0210174
Complaint, June 25, 2003--Decision, November 6, 2003*

This consent order addresses an agreement between Respondent Nestlé Holdings, Inc. -- a subsidiary of Nestle S.A., the world's largest food company -- and Respondent Dreyer's Grand Ice Cream Holdings, Inc. to combine their ice cream businesses. The order, among other things, requires the respondents to divest (1) all assets, businesses, and goodwill related to the manufacture, marketing, or sale of the Dreamery, Godiva and Whole Fruit brands, and (2) all assets related to Nestlé's distribution of frozen dessert products, to CoolBrands International, Inc. or another acquirer approved by the Commission. An accompanying Order to Maintain Assets requires the respondents to maintain the viability and marketability of the assets to be divested. In addition, the order requires the respondents, for one year, to supply CoolBrands with the types and quantities of Dreamery, Godiva, and Whole Fruit products that it requests at a price no greater than the respondents' production costs. The order also requires the respondents, at the request of CoolBrands, for one year to distribute Dreamery, Godiva, and Whole Fruit for CoolBrands in any areas of the U.S. where Respondent Dreyer's previously distributed these products.

Participants

For the Commission: *Renee S. Henning, Jill M. Frumin, Shai A. Littlejohn, Christopher L. Marvine, Samuel I. Sheinberg, Jeanne H. Liu, Catharine M. Moscatelli, Michael G. Cowie, Kenneth A. Libby, Eric D. Rohlck,, Daniel P. Ducore,, Michael Vita, Haj Hadeishi, David Schmidt, Gabe Dagen, and Art Del Buono.*

For the Respondents: *James Rill, Roxann E. Henry, John G. Calender, and Oral Pottinger, Howrey Simon Arnold & White, and Ilene Gotts and Joseph D. Larson, Wachtell, Lipton, Rosen & Katz.*

Complaint

COMPLAINT

Pursuant to the provision of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Nestlé Holdings, Inc. (“Nestlé”), Dreyer’s Grand Ice Cream Holdings, Inc., and Dreyer’s Grand Ice Cream, Inc. (Dreyer’s Grand Ice Cream Holdings, Inc., and Dreyer’s Grand Ice Cream, Inc., are hereinafter referred to as “Dreyer’s”), have entered into an agreement in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that the terms of such agreement, were they to be implemented, would result in a violation of Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. Respondent Nestle

1. Respondent Nestlé Holdings Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 383 Main Avenue, Fifth Floor, Norwalk, Connecticut 06851. Nestle Holdings, Inc., is a subsidiary of, and controlled by, Nestlé S.A., a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its principal executive offices located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland.

2. Respondent Nestlé is, and at all times relevant herein has been, among other things, engaged in the production, sales and distribution of superpremium ice cream to customers located throughout the United States.

3. Respondent Nestlé and its affiliates, in 2002, had total worldwide sales of all products of approximately 89.2 billion Swiss francs and United States sales of all products of approximately \$ 11.8 billion. Respondent Nestlé and its affiliates,

Complaint

in 2002, had United States sales of all superpremium ice cream products of approximately \$ 340 million. Nestlé sells superpremium ice cream in the United States under the Häagen-Dazs brand.

4. Respondent Nestlé is, and at all times relevant herein has been, engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

II. Respondent Dreyer's

5. Respondent Dreyer's Grand Ice Cream, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618.

6. Respondent Dreyer's Grand Ice Cream Holdings, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618. Respondent Dreyer's Grand Ice Cream Holdings, Inc., as a result of the transaction, will be the parent of Respondent Dreyer's Grand Ice Cream, Inc.

7. Respondent Dreyer's is, and at all times relevant herein has been, among other things, engaged in the production, sales, and distribution of superpremium ice cream to customers located throughout the United States.

8. Respondent Dreyer's, in 2002, had total worldwide sales of all products of approximately \$ 1.3 billion, and United States sales of all products of approximately \$ 1.3 billion. Respondent Dreyer's, in 2002, had United States sales of all superpremium ice cream products of approximately \$ 108 million. Dreyer's sells superpremium ice cream in the United States under the Dreamery, Godiva, and Starbucks brands. Dreyer's planned to introduce a

Complaint

new superpremium ice cream in the United States through its joint venture with Mars, Incorporated.

9. Respondent Dreyer's is, and at all times relevant herein has been, engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12 and Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

III. The Proposed Acquisition

10. On or about June 16, 2002, Respondents Nestlé and Dreyer's executed an agreement for Respondents Nestlé and Dreyer's to combine their ice cream businesses. The value of the proposed acquisition is approximately \$2.8 billion.

IV. The Relevant Product Market

11. The relevant product market in which it is appropriate to assess the effects of the proposed acquisition is the sale of superpremium ice cream products to the retail channel because, *inter alia*:

- (a) superpremium ice cream contains more butterfat and less air than premium or economy ice creams;
- (b) superpremium ice cream contains more expensive and higher quality ingredients than premium or economy ice creams; and
- (c) superpremium ice cream is priced significantly higher than premium or economy ice creams.

12. Total United States sales (at retail) of all superpremium ice cream products are approximately \$ 604.7 million. The parties sell superpremium ice cream products through different retail channels of distribution, including supermarkets, mass merchants, club stores, and convenience stores.

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V. The Relevant Geographic Market

13. The relevant geographic market in which it is appropriate to assess the effects of the Acquisition in the relevant line of commerce is the United States or a narrow region therein.

VI. Concentration

14. The relevant market is highly concentrated and the proposed acquisition, if consummated, will substantially increase that concentration, as follows:

(a) In the superpremium ice cream market, Nestlé has approximately a 36.5% share (in dollars) across all channels. Dreyer's has approximately a 19.1% share (in dollars) across all channels.

(b) After the acquisition, Respondents will have a market share of approximately 55.6% (in dollars) of the superpremium ice cream market identified in paragraphs 12 and 13 above.

(c) The acquisition raises the HHI from 3,501 to 4,897, an increase of 1,396 points.

VII. Conditions of Entry

15. Entry into the relevant market would not be likely, or sufficient to prevent the anticompetitive effects in the relevant market because, *inter alia*,

(a) an entrant with a new or unknown brand is unlikely to successfully take a sufficient amount of sales from superpremium ice cream incumbents to remain profitable; and

(b) a superpremium ice cream entrant would face great difficulty developing a nationwide Direct Store Delivery network comparable to either of the merging parties.

Complaint

VIII. Violations Charged

16. Nestlé and Dreyer's compete in the sale of superpremium ice cream in the United States.

17. The effect of the proposed acquisition, if consummated, may be to substantially lessen competition in the sale of superpremium ice cream in the United States in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18, in the following ways, among others:

(a) by eliminating direct competition in the sale of superpremium ice cream between Nestlé and Dreyer's;

(b) by eliminating Dreyer's as an important competitive constraint in the relevant market, *e.g.*, when Dreyer's expanded into superpremium ice cream in 1999, the price of other superpremium ice creams decreased significantly;

(c) by increasing the likelihood that the combination of Nestlé and Dreyer's will unilaterally exercise market power; and

(d) by increasing the likelihood of, or facilitation of, collusion or coordinated interaction; each of which increases the likelihood that prices will be higher with the acquisition than they would be absent the acquisition.

IX. Illegal Acquisition

18. The Agreement entered into between Respondents Nestlé and Dreyer's to combine their ice cream businesses constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18.

Complaint

WHEREFORE, THE PREMISES CONSIDERED, THE Federal Trade Commission on this twenty-fifth day of June, 2003, issues its Complaint against Respondents Nestlé and Dreyer's.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Nestlé Holdings, Inc., of certain voting securities of Respondent Dreyer's Grand Ice Cream Holdings, Inc., which as a result of the transaction will be the parent of Respondent Dreyer's Grand Ice Cream, Inc., hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents Nestlé Holdings, Inc., and Dreyer's Grand Ice Cream, Inc., with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated Section 5 of the Federal Trade Commission Act and that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and

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consideration of public comments, and having carefully considered the comments received from interested persons, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Nestlé Holdings, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 383 Main Avenue, Fifth Floor, Norwalk, Connecticut 06851. Respondent Nestlé Holdings, Inc., is a subsidiary of and controlled by Nestlé S.A., a corporation organized, existing, and doing business under, and by virtue of, the laws of Switzerland, with its principal executive offices located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland.
2. Respondent Dreyer’s Grand Ice Cream Holdings, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618.
3. Respondent Dreyer’s Grand Ice Cream, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618.
4. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

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- A. "Nestlé" means Nestlé Holdings Inc., its parent Nestlé S.A., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Nestlé Holdings Inc., including, up until the Acquisition Date, but not limited to, Nestlé Ice Cream Company, LLC ("NICC"), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Nestlé S.A." means Nestlé S.A., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Nestlé S.A., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Dreyer's" means Dreyer's Grand Ice Cream Holdings, Inc. (referred to as New December, Inc. in the Acquisition Agreement) and Dreyer's Grand Ice Cream, Inc., their directors, officers, employees, agents and representatives, predecessors, successors, and assigns; their joint ventures, subsidiaries, divisions, groups and affiliates controlled by Dreyer's Grand Ice Cream Holdings, Inc. or Dreyer's Grand Ice Cream, Inc., including from and after the Acquisition Date NICC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. "Respondents" means Nestlé and Dreyer's, individually and collectively.
- E. " Commission" means the Federal Trade Commission.
- F. "CoolBrands" means CoolBrands International Inc., a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its office and principal place of business located at 4175 Veterans

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Highway, Ronkonkoma, New York 11779. CoolBrands includes, but is not limited to, Integrated Brands, Inc.

- G. "Acquisition" means the proposed acquisition of voting securities of Dreyer's by Nestlé pursuant to the Agreement and Plan of Merger and Contribution executed by Nestlé and Dreyer's on or about June 16, 2002.
- H. "Acquisition Agreement" means the Agreement and Plan of Merger and Contribution executed by Nestlé and Dreyer's on or about June 16, 2002, as amended, pursuant to which the Acquisition is to be accomplished.
- I. "Acquisition Date" means the date that Nestlé closes its contemplated acquisition of Dreyer's stock pursuant to the Acquisition Agreement.
- J. "Commission Approved Acquirer" means the acquirer of the Assets To Be Divested which receives the prior approval of the Commission pursuant to Paragraph II of the Order, including CoolBrands unless at the time the Commission determines to make this Order final, the Commission notifies Respondents that CoolBrands is not an acceptable purchaser of the Assets To Be Divested.
- K. "Assets To Be Divested" means the Ice Cream Assets To Be Divested and the Distribution Assets. Provided, however, that Assets To Be Divested shall not include accounts receivable and cash and cash equivalents arising or accruing on or prior to the date Respondents divest the Assets To Be Divested; or inventory of raw materials, packaging materials, work in progress or finished goods of NICC.
- L. "Integrated Brands Agreement" means the Amended and Restated Asset Purchase and Sale Agreement by and among Dreyer's Grand Ice Cream, Inc., New December, Inc., Nestle Ice Cream Company, LLC and Integrated Brands, Inc., dated as of March 3, 2003, as amended on March 17,

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2003, April 16, 2003, and June 4, 2003, including all schedules and exhibits.

- M. "Divestiture Agreement" means the Integrated Brands Agreement or any other agreement for the divestiture of the Assets To Be Divested that receives the prior approval of the Commission.
- N. "Godiva ice cream" means all ice cream sold under the name "Godiva."
- O. "Dreamery" means all ice cream sold under the name "Dreamery."
- P. "Whole Fruit" means all sorbet sold under the name "Whole Fruit."
- Q. "Ice Cream Assets To Be Divested" means all of Dreyer's rights, title and interests in the assets related to Dreamery, Godiva ice cream and Whole Fruit that are included within the definition of Ice Cream Assets in the Integrated Brands Agreement. Provided, however, that all of Dreyer's rights, title and interests in all registered and unregistered trademarks, trade names and trade dress related to Dreamery products, Godiva ice cream products, and Whole Fruit products, including, but not limited to all rights of Dreyer's to the Dreamery, Cherry Chip Ba Da Bing, Fortunate Vanilla, Strawberry Fields and What Flavor Do You Dream In trade names and trademarks in the United States for any product, all rights of Dreyer's to the Godiva trade names and trademarks in the United States for any product, including all rights of Dreyer's under the License Agreement dated as of December 1, 1998 between Godiva Chocolatier, Inc., and Dreyer's, as amended, but not including the name, logo, trade dress, trademarks or tradenames of "Dreyer's" or "Edy's," are included within the definition of Ice Cream Assets To Be Divested. Provided further, that a listing of all sales of Dreamery,

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Godiva ice cream or Whole Fruit since 1999, including sales by customer and by stock keeping unit, is included within the definition of Ice Cream Assets To Be Divested.

Provided further, that all other assets of Dreyer's that relate primarily (50% or more as measured by revenue) to Dreamery, Godiva ice cream or Whole Fruit are included within the definition of Ice Cream Assets To Be Divested.

Provided further, that notwithstanding anything to the contrary in the foregoing, manufacturing plants, equipment and distribution assets are excluded from the definition of Ice Cream Assets To Be Divested.

- R. "Distribution Assets" means all assets related to the distribution of frozen dessert products by NICC, including, but not limited to, warehouses, warehouse fixtures and equipment, trucks, forklifts, pallet jacks, pallets and all permits, licenses, approvals and authorizations related to the business of distributing frozen dessert products. Provided, however, that (i) freezer cabinets; (ii) assets not exclusively related to NICC's distribution of frozen products; and (iii) retailer authorizations not related exclusively to the Ice Cream Assets To Be Divested are excluded from the definition of Distribution Assets.
- S. "Mars" means Mars, Incorporated, a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 6885 Elm Street, McLean, Virginia 22101. Mars includes, but is not limited to, Masterfoods USA, a division of Mars, Inc.
- T. "Mars Termination Agreement" means the Termination and Transition Agreement dated March 31, 2003, among Dreyer's, Mars and M&M/Mars/Dreyer's Grand Ice Cream LLC.
- U. "Starbucks" means Starbucks Corporation, a corporation organized, existing and doing business under and by virtue

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of the laws of Washington, with its office and principal place of business located at 2401 Utah Avenue South, Seattle, Washington 98134.

- V. “Ben & Jerry’s” means Ben & Jerry’s Homemade Ice Cream, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Vermont, with its office and principal place of business located at 30 Community Drive, South Burlington, Vermont 05403.
- W. “Production Cost” means the cost of manufacturing an item, including the reasonably allocated actual cost of raw materials (which includes packaging), direct labor, and reasonably allocated factory overhead.
- X. “Service Cost” means the direct material, labor and out of pocket expenses, including reasonably allocated overhead, incurred to provide the service.
- Y. “Administrative Services” means provision of certain administrative services, including but not limited to, order processing, warehousing, shipping, accounting, and information transitioning services.
- Z. “Non-Public Commission Approved Acquirer Information” means any proprietary information of the Commission Approved Acquirer related to the Assets To Be Divested or the business of the Commission Approved Acquirer obtained by Respondents in the course of fulfilling its obligations under the Order.
- AA. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity.

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II.

IT IS FURTHER ORDERED that:

- A. Respondents shall divest the Assets To Be Divested, as ongoing businesses, absolutely and in good faith, at no minimum price, to CoolBrands pursuant to and in accordance with the Divestiture Agreement no later than the later of (i) July 1, 2003 or (ii) ten (10) days after the Acquisition Date. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's. Respondents shall comply with all the terms of the Divestiture Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order or the Order to Maintain Assets), and such agreement shall be deemed incorporated by reference into this Order. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's. Failure to comply with the Divestiture Agreement shall constitute a failure to comply with this Order. Provided, however, that as to the Distribution Assets, Respondents shall not be obligated to divest those portions of the Distribution Assets that are excluded under the Integrated Brands Agreement or that CoolBrands has elected not to acquire pursuant to the Integrated Brands Agreement. Provided further, that Respondents may license back from CoolBrands the rights to use the "Whole Fruit" name, logo, trademark, and trade dress solely in connection with the manufacture, distribution and sale of fruit bars for a period not to exceed one (1) year. Provided further, that if any document or other material included within the Assets To Be Divested is required to be retained by Respondents by requirements of law, or for tax purposes or for defending lawsuits, Respondents may retain a copy of such materials for use only for such purposes.
- B. Provided, however, that if Respondents divest the Assets To Be Divested to CoolBrands prior to the date this Order

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becomes final, Respondents will include and enforce a provision in the Divestiture Agreement requiring that the transaction be rescinded if the Commission determines not to make the Order final or if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that CoolBrands is not an acceptable purchaser of the Assets To Be Divested or that the manner in which the divestiture was accomplished is not an acceptable manner of divestiture. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's. Provided further, that if the Commission so notifies Respondents, Respondents shall immediately rescind the transaction with CoolBrands and shall divest the Assets To Be Divested within 120 days of the date the Order becomes final to a Commission Approved Acquirer pursuant to a Divestiture Agreement that receives the prior approval of the Commission. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's. Respondents shall comply with all the terms of the Divestiture Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order or the Order to Maintain Assets), and such agreement shall be deemed incorporated by reference into this Order. Failure to comply with the Divestiture Agreement shall constitute a failure to comply with this Order. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's. Provided further, that as to the Distribution Assets, Respondents shall not be obligated to divest those portions of the Distribution Assets that the Commission Approved Acquirer has elected not to acquire pursuant to the Divestiture Agreement. Provided further, that Respondents may license back from the Commission Approved Acquirer the rights to use the "Whole Fruit" name, logo, trademark, and trade dress solely in connection with the manufacture, distribution and sale of fruit bars for a period not to exceed one (1) year. Provided further, that if

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any document or other material included within the Assets To Be Divested is required to be retained by Respondents by requirements of law or for tax purposes or for defending lawsuits, Respondents may retain a copy of such materials for use only for such purposes.

- C. Dreyer's shall obtain the consent of Godiva Chocolatier, Inc., to the assignment of the License Agreement dated as of December 1, 1998 between Godiva Chocolatier, Inc., and Dreyer's, as amended, to the Commission Approved Acquirer prior to closing on the Divestiture Agreement.
- D. Pending divestiture of the Assets To Be Divested, Respondents shall take such actions as are reasonably necessary to maintain the viability and marketability of the Assets To Be Divested and to prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer, or impairment of any of the Assets To Be Divested, except for ordinary wear and tear and as would otherwise occur in the ordinary course of business. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's.
- E. At the request of the Commission Approved Acquirer, for a period not to exceed one (1) year from the date Respondents divest the Assets To Be Divested, Dreyer's shall supply such types and quantities of Dreamery, Godiva ice cream and Whole Fruit as are requested by the Commission Approved Acquirer at a price that does not exceed Dreyer's Production Costs. In supplying product to the Commission Approved Acquirer, Dreyer's shall give priority to the demand for product of the Commission Approved Acquirer.
- F. At the request of the Commission Approved Acquirer, for a period not to exceed one (1) year from the date Respondents divest the Assets To Be Divested, Dreyer's shall distribute Dreamery, Godiva ice cream and Whole Fruit for the Commission Approved Acquirer in any of those areas of the

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country where prior to the Acquisition Dreyer's distributed the products itself at a price that does not exceed Dreyer's Service Costs. In distributing product for the Commission Approved Acquirer, Dreyer's shall utilize its distribution assets in an efficient manner and shall not discriminate against the Commission Approved Acquirer and in favor of its own products. Provided, however, that nothing in this Order shall prohibit Respondents from entering into contracts or arrangements in the ordinary course of business to distribute product for the Commission Approved Acquirer for periods beyond one (1) year.

- G. At the request of the Commission Approved Acquirer, for a period not to exceed one (1) year from the date Respondents divest the Assets To Be Divested, Dreyer's shall provide technical assistance to the Commission Approved Acquirer to enable the Commission Approved Acquirer to manufacture Dreamery, Godiva ice cream and Whole Fruit to the same quality and at the same efficiency as achieved by Dreyer's prior to the Acquisition. In providing technical assistance to the Commission Approved Acquirer, Dreyer's shall charge no more than its Service Cost of providing the technical assistance. Among other things, Dreyer's shall allow the Commission Approved Acquirer reasonable and timely access to Dreyer's manufacturing facilities for the purpose of inspecting manufacturing operations relating to the production of Dreamery, Godiva ice cream and Whole Fruit.
- H. At the request of the Commission Approved Acquirer, for a period not to exceed one (1) year from the date Respondents divest the Assets To Be Divested, Dreyer's shall provide Administrative Services to the Commission Approved Acquirer sufficient to enable the Commission Approved Acquirer to operate the Assets To Be Divested in a viable and competitive manner. In providing Administrative Services to the Commission Approved Acquirer, Dreyer's

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shall charge no more than its Service Cost of providing the Administrative Services.

- I. At the request of the Commission Approved Acquirer, Dreyer's shall enter into an agreement with the Commission Approved Acquirer for a period not to exceed five (5) years whereby Dreyer's will supply sufficient volumes of frozen dessert products to the Commission Approved Acquirer in a manner designed to enable the Commission Approved Acquirer to operate the Distribution Assets at a profit. Entry into and compliance with the Integrated Brands Agreement meets this requirement.
- J. Within ten (10) days of the date this Order becomes final, Dreyer's shall modify the joint venture agreement between Dreyer's and Starbucks to make it a non-exclusive joint venture and allow Starbucks to manufacture, distribute and sell ice cream, including ice cream under the "Starbucks" trade name, apart from the joint venture.
- K. The purpose of the divestiture of the Assets To Be Divested is to ensure the continued use of the Assets To Be Divested in the same business in which such assets were engaged at the time of the announcement of the Acquisition by Respondents and to remedy the lessening of competition that would result from the Acquisition as alleged in the Commission's complaint.

III.

IT IS FURTHER ORDERED that:

- A. Except in the course of performing their obligations under this Order or the Divestiture Agreement, Respondents shall not provide, disclose or otherwise make available any Non-Public Commission Approved Acquirer Information to any Person and shall not use any Non-Public Commission Approved Acquirer Information for any reason or purpose.

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- B. Respondents shall disclose Non-Public Commission Approved Acquirer Information only to those Persons who require such information for the purposes of fulfilling Respondents' obligations under this Order or the Divestiture Agreement, and only such part of the Non-Public Commission Approved Acquirer Information that is so required.
- C. Respondents shall enforce the terms of this Paragraph III as to any Person and take such action as is necessary to cause each such Person to comply with the requirements of this Paragraph III, including all actions that Respondents would take to protect their own trade secrets and proprietary information.
- D. The requirements of this Paragraph III do not apply to that part of the Non-Public Commission Approved Acquirer Information that Respondents demonstrate (i) was or becomes generally available to the public other than as a result of a disclosure by Respondents; (ii) was available, or becomes available, to Respondents on a non-confidential basis, but only if, to the knowledge of Respondents, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information; or (iii) was independently developed by Respondents without reference to any Non-Public Commission Approved Acquirer Information.

IV.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order.

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- B. If an Interim Monitor is appointed pursuant to Paragraph IV.A. of this Order, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:
1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor;
 2. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission;
 3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the terms of this Order in a manner consistent with the purposes of this Order;
 4. The Interim Monitor shall serve until the last obligations under Paragraph II of this Order have been fully performed other than any indemnification or breach obligations under such agreements; provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order;

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5. The Interim Monitor shall have full and complete access, subject to any legally recognized privilege of Respondents, to Respondents' personnel, books, records, documents, facilities and technical information relating to the research, development and manufacture of Dreamery, Godiva ice Cream or Whole Fruit, or to any other relevant information, as the Interim Monitor may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Dreamery, Godiva ice Cream or Whole Fruit. Respondents shall cooperate with any reasonable request of the Interim Monitor. Respondents shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with this Order;
6. The Interim Monitor shall serve, without bond or other security, at the expense of Dreyer's, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor will be obligated to sign an appropriate confidentiality agreement relating to performance of the Interim Monitor's duties. The Interim Monitor shall have authority to employ, at the expense of Dreyer's, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission;
7. Dreyer's shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance,

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gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;

8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in Paragraph IV.A. of this Order.
9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order;
10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph IX of this Order and/or as otherwise provided in any trust agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to it by the Respondents. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of this Order. These responsibilities of the Interim Monitor shall continue until the last obligations under the Order have been fully performed, unless otherwise directed by the Commission.

V.

IT IS FURTHER ORDERED that:

- A. If Respondents have not divested, absolutely and in good faith, the Assets To Be Divested within the time period required by Paragraph II of this Order, the Commission may appoint a trustee to divest the Assets To Be Divested in a manner that satisfies the requirements of Paragraph II.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade

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Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.

- C. If a trustee is appointed by the Commission or a court pursuant to Paragraph V.A. of this Order, Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:
1. The Commission shall select the trustee, subject to the consent of the Respondents, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of written notice by the staff of the Commission to Respondents of the identity of any proposed trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee. The trustee may be the same person or entity as any trustee appointed pursuant to the Order to Maintain Assets.
 2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest the Assets To Be Divested.
 3. Within ten (10) days after appointment of the trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee

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all rights and powers necessary to permit the trustee to effect the divestitures required by this Order.

4. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph V. C. 3. to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time or that consents can be obtained in a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend this period only two (2) times.
5. The trustee shall have full and complete access, subject to any legally recognized privilege of Respondents, to the personnel, books, records and facilities related to the Assets To Be Divested or to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.
6. The trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, but shall divest expeditiously at no minimum price. The divestitures shall be made only to an acquirer that receives the prior approval of the Commission, and the divestitures and consents shall be accomplished only in a manner that receives the prior approval of the Commission; provided, however, if the

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trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the trustee shall divest to the acquiring entity or entities selected by Respondents from among those approved by the Commission; provided further, however, that Respondents shall select such entity within five (5) days of receiving written notification of the Commission's approval.

7. The trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Assets To Be Divested.
8. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

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9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph V.A. of this Order.
10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures required by this Order.
11. The trustee may also divest such additional ancillary assets and effect such arrangements related to the Assets To Be Divested, as approved by the Commission, that the trustee demonstrates are necessary to accomplish divestiture of the Assets To Be Divested.
12. The trustee shall have no obligation or authority to operate or maintain the Assets To Be Divested.
13. The trustee shall report in writing to Respondents and the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestitures and to obtain the necessary consents.

VI.

IT IS FURTHER ORDERED that Dreyer's shall allow Mars to terminate its agreements and joint ventures with Dreyer's without paying any termination fees or expenses pursuant to and in accordance with the Mars Termination Agreement. Dreyer's shall comply with all the terms of the Mars Termination Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order or the Order to Maintain Assets), and such agreement shall be deemed incorporated by reference into this Order. Failure to comply with the Mars Termination Agreement shall constitute a failure to comply with this Order. Prior to the dissolution of the agreements and joint venture between Mars and Dreyer's, as enumerated in the Mars

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Termination Agreement, Dreyer's shall fully comply with its obligations under the agreements and joint venture. In the conduct of its business, Dreyer's will not discriminate against Mars and in favor of its own products in connection with fulfilling its obligations under the agreements and joint venture referred to herein.

VII.

IT IS FURTHER ORDERED that Dreyer's shall allow Ben & Jerry's to terminate its distribution agreement with Dreyer's effective December 31, 2003 without paying any termination fees or expenses, provided that Ben & Jerry's gives written notice to Dreyer's requesting such termination by July 31, 2003. Prior to the termination of the distribution agreement, Dreyer's shall fully comply with its obligations under the agreement. In the conduct of its business, Dreyer's will not discriminate against Ben & Jerry's and in favor of its own products in connection with fulfilling its obligations under the distribution agreement referred to herein.

VIII.

IT IS FURTHER ORDERED that, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, (A) any ownership, leasehold, or other interest, in whole or in part, in any of the Assets To Be Divested except as provided in Section 2.4(c) of the Integrated Brands Agreement; or (B) any ownership, leasehold, or other interest, in whole or in part, in any Person engaged in the distribution of ice cream through direct store delivery in the United States (excluding Puerto Rico), where the consideration paid is \$7,500,000 or more.

Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code

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of Federal Regulations as amended (hereinafter referred to as “the Notification”), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after submitting such additional information or documentary material. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Provided, however, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

IX.

IT IS FURTHER ORDERED that, within thirty (30) days after the date this Order becomes final and every sixty (60) days thereafter until Respondents have fully complied with the provisions of Paragraphs II.A through II.H. and II.J. of this Order, and annually thereafter on the anniversary of the date this Order becomes final, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with their respective obligations under this Order and the Order to Maintain Assets. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply

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with the Order, including a description of all substantive contacts or negotiations relating to the divestitures and the approvals. Respondents shall include in their compliance reports copies, other than of privileged materials, of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the divestitures and approvals.

X.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

XI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

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XII.

IT IS FURTHER ORDERED that this Order shall terminate on November 6, 2013.

By the Commission, Commissioner Harbour not participating.

Order

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Nestlé Holdings, Inc., of certain voting securities of Respondent Dreyer's Grand Ice Cream Holdings, Inc., which as a result of the transaction will be the parent of Respondent Dreyer's Grand Ice Cream, Inc., hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents Nestlé Holdings, Inc., and Dreyer's Grand Ice Cream, Inc., with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated Section 5 of the Federal Trade Commission Act and that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement containing the Decision and Order on the public record for a period of thirty (30) days, the

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Commission hereby issues its Complaint, makes the following jurisdictional finding and issues this Order to Maintain Assets:

1. Respondent Nestlé Holdings, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 383 Main Avenue, Fifth Floor, Norwalk, Connecticut 06851. Respondent Nestlé Holdings, Inc., is a subsidiary of and controlled by Nestlé S.A., a corporation organized, existing, and doing business under, and by virtue of, the laws of Switzerland, with its principal executive offices located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland.
2. Respondent Dreyer's Grand Ice Cream Holdings, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618.
3. Respondent Dreyer's Grand Ice Cream, Inc., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 5929 College Avenue, Oakland, California 94618.
4. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions shall apply:

- A. "Nestlé" means Nestlé Holdings Inc., its parent Nestlé S.A., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by

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Nestlé Holdings Inc., including, up until the Acquisition Date, but not limited to, Nestlé Ice Cream Company, LLC (“NICC”), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- B. “Nestlé S.A.” means Nestlé S.A., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Nestlé S.A., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. " Dreyer's" means Dreyer's Grand Ice Cream Holdings, Inc. (referred to as New December, Inc. in the Acquisition Agreement) and Dreyer's Grand Ice Cream, Inc., their directors, officers, employees, agents and representatives, predecessors, successors, and assigns; their joint ventures, subsidiaries, divisions, groups and affiliates controlled by Dreyer's Grand Ice Cream Holdings, Inc. or Dreyer's Grand Ice Cream, Inc., including from and after the Acquisition Date NICC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. "Respondents" means Nestlé and Dreyer's, individually and collectively.
- E. "Commission" means the Federal Trade Commission.
- F. "CoolBrands" means CoolBrands International Inc., a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its office and principal place of business located at 4175 Veterans Highway, Ronkonkoma, New York 11779. CoolBrands includes, but is not limited to, Integrated Brands, Inc.
- G. "Acquisition" means the proposed acquisition of voting securities of Dreyer's by Nestlé pursuant to the Agreement

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and Plan of Merger and Contribution executed by Nestlé and Dreyer's on or about June 16, 2002.

- H. "Acquisition Agreement" means the Agreement and Plan of Merger and Contribution executed by Nestlé and Dreyer's on or about June 16, 2002, as amended, pursuant to which the Acquisition is to be accomplished.
- I. "Acquisition Date" means the date that Nestlé closes its contemplated acquisition of Dreyer's stock pursuant to the Acquisition Agreement.
- J. "Commission Approved Acquirer" means the acquirer of the Assets To Be Divested which receives the prior approval of the Commission pursuant to Paragraph II of the Decision and Order, including CoolBrands unless at the time the Commission determines to make the Decision and Order final, the Commission notifies Respondents that CoolBrands is not an acceptable purchaser of the Assets To Be Divested.
- K. "Assets To Be Divested" means the Ice Cream Assets To Be Divested and the Distribution Assets.
- L. "Material Confidential Information" means competitively sensitive or proprietary information not independently known to an entity from sources other than the entity to which the information pertains, and includes, but is not limited to, all customer lists, price lists, marketing methods, patents, technologies, processes, know-how, or other trade secrets.

Provided, however, any term used in this Order to Maintain Assets that is not otherwise defined in this Paragraph I has the same meaning as defined in the Consent Agreement and the Decision and Order.

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II.

IT IS FURTHER ORDERED that:

- A. Respondents shall take such actions as are reasonably necessary to maintain the viability and marketability of the Assets To Be Divested, and to prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer or impairment of any of the Assets To Be Divested, except for ordinary wear and tear and as would otherwise occur in the ordinary course of business. Provided, however, that from and after the Acquisition Date, this obligation shall be the responsibility of Dreyer's.
- B. Except to the extent necessary to assure compliance with this Order to Maintain Assets, the Consent Agreement, and the Decision and Order, Respondents shall not allow any person not involved in the management or operations of the Assets To Be Divested to have access to any Material Confidential Information concerning the Assets To Be Divested.

III.

IT IS FURTHER ORDERED that:

- A. At any time after the Commission issues this Order to Maintain Assets (hereinafter "Order"), the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order.
- B. If an Interim Monitor is appointed pursuant to Paragraph III.A. of this Order, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

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1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor;
2. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission;
3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the terms of this Order in a manner consistent with the purposes of this Order;
4. The Interim Monitor shall serve until the last obligations under the Order have been fully performed other than any indemnification or breach obligations under such agreements; provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order;
5. The Interim Monitor shall have full and complete access, subject to any legally recognized privilege of Respondents, to Respondents' personnel, books, records, documents, facilities and technical information relating to the research, development and manufacture of Dreamery, Godiva ice cream or Whole Fruit, or to any other relevant information,

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as the Interim Monitor may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Dreamery, Godiva ice cream or Whole Fruit. Respondents shall cooperate with any reasonable request of the Interim Monitor. Respondents shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with this Order;

6. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor will be obligated to sign an appropriate confidentiality agreement relating to performance of the Interim Monitor's duties. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission;
7. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;
8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may

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appoint a substitute Interim Monitor in the same manner as provided in Paragraph III.A. of this Order.

9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order;
 10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph III.B. of this Order and/or as otherwise provided in any trust agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to it by the Respondents. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of this Order. These responsibilities of the Interim Monitor shall continue until the last obligations under the Order have been fully performed, unless otherwise directed by the Commission.
- C. The Interim Monitor appointed pursuant to Paragraph III.A. of this Order to Maintain Assets or Paragraph IV.A. of the Decision and Order may be the same person appointed as the trustee pursuant to Paragraph V.A. of the Decision and Order in this matter.

IV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order.

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V.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

VI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. Three (3) business days after the divestiture of the Assets To Be Divested pursuant to Paragraph II or Paragraph V of the Decision and Order. Provided, however, that if Respondents divest the Assets To Be Divested to CoolBrands prior to the date the Commission issues the Decision and Order, and if at the time the Commission issues the Decision and Order it notifies Respondents that CoolBrands is not an acceptable acquirer of the Assets To Be Divested or that the manner in which the divestiture was

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accomplished was not acceptable, then Respondents must comply with this Order and this Order shall then terminate three (3) business days after the subsequent divestiture of the Assets To Be Divested pursuant to Paragraph II or Paragraph V of the Decision and Order.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted for public comment from Nestlé Holdings, Inc. (“Nestlé”), Dreyer’s Grand Ice Cream Holdings, Inc., and Dreyer’s Grand Ice Cream, Inc. (“Dreyer’s”) (collectively, “Proposed Respondents”), an Agreement Containing Consent Order (“Proposed Consent Agreement”) including the Decision and Order (“Proposed Order”) and the Order to Maintain Assets. The Proposed Respondents have also reviewed a draft complaint. The Commission has now issued the complaint and Proposed Order. The Proposed Consent Agreement is designed to remedy the likely anticompetitive effects arising from the merger of Nestlé and Dreyer’s.

II. The Parties and the Transaction

Nestlé S.A., the world’s largest food company, is headquartered in Switzerland. Nestlé Holdings, Inc., a wholly owned subsidiary of Nestlé S.A., manufactures, distributes, and sells the Häagen-Dazs brand of superpremium ice cream, as well as such frozen novelty products as Drumstick, Bon Bons, IceScreamers, Dole Fruit Bars, Butterfinger ice cream bars, and the Nestlé Crunch Bar. Sales in 2001 of all Nestlé ice cream products totaled approximately \$800 million.

Dreyer’s manufactures, distributes, and sells the Dreamery brand of superpremium ice cream, as well as the Godiva brand of superpremium ice cream under a long-term license with Godiva Chocolatier, Inc., and the Starbucks brand of superpremium ice cream products under a joint venture with Starbucks Corporation. Dreyer’s also manufactures, distributes and sells such other products as the Dreyer’s brand of premium ice cream in thirteen western states and Texas, the Edy’s brand of premium ice cream throughout the remaining regions of the United States, and the Whole Fruit line of sorbet. Dreyer’s total sales in 2001 were

Analysis

approximately \$1.4 billion. As a result of the transaction, Respondent Dreyer's Grand Ice Cream Holdings, Inc., will be the parent of Respondent Dreyer's Grand Ice Cream, Inc.

On June 16, 2002, Nestlé and Dreyer's signed an Agreement and Plan of Merger and Contribution whereby Nestlé and Dreyer's would combine their ice cream businesses. The transaction will increase Nestlé's interest in Dreyer's from 23 percent to approximately 67 percent. At the time Nestlé and Dreyer's announced the merger, the transaction was valued at approximately \$2.8 billion.

III. The Complaint

The complaint alleges that the relevant line of commerce (*i.e.*, the product market) in which to analyze the acquisition is the sale of superpremium ice cream to the retail channel. Superpremium ice cream contains more butterfat and less air than premium or economy ice creams. Therefore, superpremium ice cream is higher in fat than the other two segments of ice cream. Ice cream also is differentiated on the quality of ingredients, with superpremium containing more expensive and higher quality inputs. Finally, superpremium ice cream is priced significantly higher than premium or economy ice creams. Superpremium ice cream manufacturers set their prices based on various factors, including the price of other superpremium ice creams. When Dreyer's expanded into superpremium ice cream in 1999, the price of other superpremium ice creams declined.

The complaint alleges that the relevant geographic market in which there are competitive problems related to the acquisition is the United States. The superpremium ice cream market is highly concentrated when measured by the Herfindahl-Hirschman Index (commonly referred to as the "HHI").¹ The post-acquisition HHI

¹ The HHI is a measurement of market concentration calculated by summing the squares of the individual market shares

Analysis

would increase over 1,600 points, from 3,501 to 4897 and the merging parties would have a combined market share of over 55%.

The complaint further alleges that entry would not be likely or sufficient to prevent anticompetitive effects in the United States. It would be very difficult for an entrant with a new or unknown brand to successfully take a sufficient amount of sales from superpremium ice cream incumbents to remain profitable. Furthermore, a superpremium ice cream entrant would face great difficulty developing a nationwide Direct Store Delivery (“DSD”) distribution network comparable to either of the merging parties.

The complaint also alleges that Nestlé’s acquisition of Dreyer’s, if consummated, may substantially lessen competition in the relevant line of commerce in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 45, by eliminating direct competition between Nestlé and Dreyer’s; by eliminating Dreyer’s as an important competitive constraint in the relevant market; by increasing the likelihood that the combined Nestlé/Dreyer’s will unilaterally exercise market power; and by increasing the likelihood of, or facilitation of, collusion or coordinated interaction in the United States.

IV. The Terms of the Agreement Containing Consent Order

The Proposed Consent Agreement will remedy the Commission’s competitive concerns about the proposed acquisition. Proposed Consent Agreement Paragraph II.A. requires that Proposed Respondents divest: (1) all assets, businesses, and goodwill related to the manufacture, marketing, or sale of the Dreamery, Godiva and Whole Fruit brands, and (2) all assets related to Nestlé’s distribution of frozen dessert products. These assets, collectively referred to as the “assets to be divested,” will be divested to CoolBrands International, Inc. (“CoolBrands”)

of all participants.

Analysis

no later than ten (10) days after Nestlé acquires Dreyer's. Proposed Respondents are not obligated to divest those Nestlé distribution assets that CoolBrands elects not to acquire. Proposed Respondents may license back from CoolBrands the rights to use the "Whole Fruit" name for fruit bars for a period not to exceed one (1) year.

The Proposed Consent Agreement requires Proposed Respondents to divest Nestlé's distribution assets to CoolBrands because virtually all superpremium ice cream currently is sold through DSD. This means that the distributor physically places the product on retailers' shelves, and the retailer does not purchase the product until after it is actually delivered to the store.

Paragraph II.B. provides that if the Commission determines that CoolBrands is not an acceptable purchaser of the assets to be divested, or if the divestiture is not accomplished in an acceptable manner, Proposed Respondents shall immediately rescind the sale of the assets to be divested to CoolBrands and divest those assets at no minimum price to another purchaser that receives the prior approval of the Commission within 120 days of the date the Order becomes final.

Paragraph II.C. of the Proposed Consent Agreement requires that, prior to divesting, Proposed Respondents obtain the consent of Godiva Chocolatier, Inc. ("Godiva Chocolatier"), to the assignment of the license agreement between Godiva Chocolatier and Dreyer's for the manufacture, distribution and sale of Godiva ice cream to the acquirer.

Paragraph II.D. of the Proposed Consent Agreement requires Proposed Respondents to maintain the viability and marketability of the assets to be divested. The proposed respondents are also required to maintain the assets pursuant to the Order to Maintain Assets. Paragraph II.E. requires that for a period not to exceed one (1) year from the date that CoolBrands obtains the assets to be divested, Proposed Respondents will supply CoolBrands with the types and quantities of Dreamery, Godiva, and Whole Fruit

Analysis

products that CoolBrands requests at a price no greater than Proposed Respondents' production costs. Paragraph II.F. further provides that at the request of CoolBrands, Proposed Respondents will distribute Dreamery, Godiva, and Whole Fruit for CoolBrands for a period not to exceed one (1) year in any areas of the U.S. where Dreyer's previously distributed these products. Paragraph II.G. requires Proposed Respondents to provide technical assistance to CoolBrands, as needed, for a period not to exceed one (1) year. Paragraph II.H. requires Proposed Respondents to provide administrative services to CoolBrands, as needed, for a period not to exceed one (1) year.

Paragraph II.I. requires that, for a period not to exceed five (5) years, Proposed Respondents will supply sufficient volumes of additional ice cream products (*e.g.*, premium ice creams or novelty products) to CoolBrands to enable CoolBrands to profitably distribute Dreamery, Godiva, and Whole Fruit superpremium products. This provision was included in the Proposed Consent Agreement because Nestlé's DSD system handles more products than the Dreamery, Godiva, and Whole Fruit superpremium products that CoolBrands is acquiring, and the provision will enable CoolBrands to operate profitably for a limited term while CoolBrands attempts to attract independent distribution business from unaffiliated third parties.

Paragraph II.J. requires that Proposed Respondents modify the joint venture agreement between Dreyer's and Starbucks to allow Starbucks to manufacture, distribute, and sell the Starbucks brand of ice cream and other ice cream products themselves or in collaboration with other third-parties. Under the existing joint venture agreement between Dreyer's and Starbucks, Dreyer's is the sole manufacturer, distributor and salesman for the Starbucks brand of superpremium ice cream.

Paragraph III limits the ways in which Proposed Respondents may utilize an information it acquires with respect to CoolBrands.

Paragraph IV of the Proposed Consent Agreement allows the

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Commission to appoint an Interim Monitor to monitor compliance with the terms of this Proposed Order. The Proposed Consent Agreement provides the Monitor Trustee with the power and authority to monitor the Proposed Respondents' compliance with the terms of the Proposed Consent Agreement, and full and complete access to personnel, books, records, documents, and facilities of the Proposed Respondents to fulfill that responsibility. In addition, the Interim Monitor may request any other relevant information that relates to the Proposed Respondents' obligations under the Proposed Consent Agreement. The Proposed Consent Agreement precludes Proposed Respondents from taking any action to interfere with or impede the Interim Monitor's ability to perform his or her responsibilities or to monitor compliance with the Proposed Consent Agreement.

The Interim Monitor may hire such consultants, accountants, attorneys, and other assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Proposed Consent Agreement requires the Proposed Respondents to bear the cost and expense of hiring these assistants.

Paragraph V.A. of the Proposed Consent Agreement authorizes the Commission to appoint a divestiture trustee in the event Nestlé fails to divest the assets as required by the Proposed Consent Agreement.

Paragraph VI. of the Proposed Consent Agreement provides that Proposed Respondents allow, Mars, Incorporated ("Mars"), to terminate its agreements and joint ventures with Dreyer's. Mars' agreements with Dreyer's involved Dreyer's manufacturing and distributing ice cream products for Mars. Mars planned to have Dreyer's manufacture and distribute a new superpremium ice cream for Mars. Mars will now be free to enter this market on their own or as part of a new joint venture, or other arrangement, with a third party.

Paragraph VII. of the Proposed Consent Agreement requires Proposed Respondents to permit Unilever's Ben & Jerry's

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subsidiary to terminate its distribution agreement with Dreyer's by December 31, 2003. The existing distribution agreement between Dreyer's & Ben & Jerry's required Ben & Jerry's to give Dreyer's approximately nine (9) months notice prior to terminating distribution. This provision will reduce the notice period that Ben & Jerry's must provide.

Paragraph VIII. through XII. detail certain general provisions. Paragraph VIII. prohibits Proposed Respondents from acquiring, without providing the Commission with prior notice, any ownership or other interest in Dreamery, Godiva, or Starbucks superpremium ice cream brands or in any of the Nestlé distribution assets that CoolBrands is acquiring, or other DSD distribution assets. These are the assets that Proposed Respondents are divesting. The provisions regarding prior notice are consistent with the terms used in prior orders. The Proposed Consent Agreement does not restrict the Proposed Respondents from developing any new superpremium brands.

Paragraph IX. requires the Proposed Respondents to file compliance reports with the Commission, the first of which is due within thirty (30) days of the date on which the Proposed Consent Agreement becomes final, and every sixty (60) days thereafter until the divestitures are completed. Paragraph X. provides for notification to the Commission in the event of any changes in the corporate Proposed Respondents. Paragraph XI. requires Proposed Respondents to grant access to any authorized Commission representative for the purpose of determining or securing compliance with the Proposed Consent Agreement. Paragraph XII. terminates the Proposed Consent Agreement after ten (10) years from the date the Proposed Order becomes final.

V. Opportunity for Public Comment

The Proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the

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Commission will again review the Proposed Consent Agreement and the comments received and will decide whether it should withdraw from the agreement or make the Proposed Consent Agreement final.

By accepting the Proposed Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the Proposed Consent Agreement, including the proposed sale of assets to CoolBrands, in order to aid the Commission in its determination of whether to make the Proposed Consent Agreement final. This analysis is not intended to constitute an official interpretation of the Proposed Consent Agreement nor is it intended to modify the terms of the Proposed Consent Agreement in any way.

Complaint

IN THE MATTER OF

SURGICAL SPECIALISTS OF YAKIMA, P.L.L.C., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4101; File No. 0210242**Complaint, November 14, 2003--Decision, November 14, 2003*

This consent order, among other things, prohibits Respondent Surgical Specialists of Yakima ("SSY") -- which has 24 physician members in South Central Washington State that practice in five specialties: Ear Nose and Throat, OB/GYN, Ophthalmology, Plastic Surgery, and General Surgery -- and Cascade Surgical Partners ("CSP") and Respondent Yakima Surgical Associates ("YSA"), which are members of SSY -- from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, to refuse to deal, or to threaten to refuse to deal with payors; (3) regarding the terms of dealing with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving SSY. The order also prohibits the respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to deal with a payor, and from attempting to engage in, or from inducing anyone to engage in, any action prohibited by the order. In addition, the order requires Respondent SSY to revoke the membership of either CSP or YSA; to distribute the complaint and order to all physicians who have participated in SSY, and to payors that negotiated or indicated an interest in negotiating contracts with SSY; and to terminate, at any payor's request and without penalty, its current contracts with respect to providing physician services.

Participants

For the Commission: *Joseph Lipinsky, Robert J. Schroeder, Charles A. Harwood, D. Bruce Hoffman, Louis Silvia and Mary T. Coleman.*

For the Respondents: *Douglas C. Ross, Davis Wright Tremaine, LLP.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended (“FTC Act”), 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Surgical Specialists of Yakima, P.L.L.C. (“SSY”), Cascade Surgical Partners, Inc., P.S. (“Cascade Surgical”), and Yakima Surgical Associates, Inc., P.S. (“Yakima Surgical”), hereinafter collectively referred to as “Respondents,” have violated Section 5 of the FTC Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

NATURE OF THE CASE

1. This matter concerns horizontal agreements among competing physicians who constitute most of the physicians who specialize in general surgery in the Yakima, Washington, area, to fix price and other terms charged to health care plans and other third-party payors (“payors”). In furtherance of their agreements, the physicians formed SSY to negotiate and to enter into contracts with payors upon collectively agreed upon price and other contract terms. The physicians further agreed to refuse to negotiate or to contract individually with any payor. This conduct raised the price of physician services for surgery in the Yakima, Washington, area.

RESPONDENTS

2. Respondent SSY is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 307 South 12th Avenue, Yakima, WA 98902. SSY’s Executive Committee (“Committee”) consists of the organization’s officers: the President, Vice President, Treasurer, Secretary, and three Members-at-Large. The Committee generally has negotiated and reviewed proposed payor contracts prior to submitting any

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information to SSY's physician members. Once a proposed contract has been submitted to the physician members, however, they have voted on whether to accept it. Once the terms of a payor's contract have been accepted by a majority of SSY's members, the Committee then has signed that contract on behalf of the members.

3. Respondent Cascade Surgical is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 3003 Tieton Drive, Yakima, WA 98902. Its membership consists of four physicians who specialize in general surgery. Respondent Cascade Surgical is a member of Respondent SSY.

4. Respondent Yakima Surgical is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 111 South 11th Avenue, Yakima, WA 98902. Its membership consists of five physicians who specialize in general surgery. Respondent Yakima Surgical is a member of Respondent SSY.

5. Except to the extent that competition has been restrained as alleged herein, Respondents Cascade Surgical and Yakima Surgical have been, and are now, in competition with each other for the provision of physician services.

THE FTC HAS JURISDICTION OVER RESPONDENTS

6. Respondents' general business practices, including the acts and practices herein alleged, are in or affecting "commerce" as defined in the FTC Act, as amended, 15 U.S.C. § 44.

**OVERVIEW OF MARKET AND PHYSICIAN
COMPETITION**

7. SSY has approximately 24 physician members, all of whom are licensed to practice medicine in the State of Washington, and are engaged in the business of providing physician services to

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patients in the Yakima, Washington area. SSY's physicians practice in the following specialties: ENT, OB/GYN, General Surgery, Ophthalmology, and Plastic Surgery. There are ten physicians who specialize in general surgery in the Yakima, Washington area – Yakima Surgical's five surgeons, Cascade Surgical's four surgeons, and one independent surgeon who is not a member of SSY. Thus, SSY has 90% of the physicians who specialize in general surgery who practice in the Yakima, Washington area.

8. The area centers on the Yakima Valley and extends from the Cascade Mountain Range to the Columbia River. The area's largest city, Yakima, with a population of 72,000, is the processing and shipping hub for the produce grown in the Yakima Valley. Other communities in the Yakima, Washington area include Sunnyside and Toppenish, headquarters for the Yakima Indian Nation. To be competitively marketable in the Yakima, Washington area, a payor's health insurance plan must include in its physician network a large number of general surgery physicians who practice in the Yakima, Washington area.

9. Physicians often contract with payors to establish the terms and conditions, including price terms, under which the physicians will render services to the payors' subscribers. Physicians entering into such contracts often agree to lower compensation in order to obtain access to additional patients made available by the payors' relationship with insureds. These contracts may reduce payors' costs and enable them to lower the price of insurance, and reduce out-of-pocket medical care expenditures by subscribers to the payors' health insurance plans.

10. Physicians organize their practices under several models, including, but not limited to, sole proprietorships, partnerships, and professional corporations (collectively "physician entities"). Absent agreements among competing physician entities on the terms, including price, on which they will provide services to enrollees in payors' health care plans, competing physician entities decide individually whether to enter into payor contracts

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to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

11. The Medicare Resource Based Relative Value Scale (“RBRVS”) is a system used by the Centers for Medicare and Medicaid Services (“CMS”) to determine the amount to pay physicians for the services they render to Medicare patients. Under RBRVS, the price for physician services is determined by multiplying a dollar conversion factor, set by CMS, by the Relative Value Unit (“RVU”) assigned by CMS to each physician service (*e.g.*, under RBRVS, a Medicare conversion factor of \$35 x 2.34 RVU for a physician service = an \$82 fee). Payors in many areas of the country make contract offers to individual physicians or groups at a price level specified as some percentage of the RBRVS fee for a particular year (*e.g.*, “110% of 2003 RBRVS”). In the Yakima, Washington area, payors negotiate the conversion factor, rather than a percentage of the RBRVS fee, with physicians. For example, if a Yakima, Washington area payor offers a conversion factor of \$42, rather than the Medicare conversion factor of \$35, and the RVU that CMS assigns for a particular physician service is 2.34, then the physician’s price for that service to the payor would be \$42 x 2.34, or \$98.28.

**SSY WAS FORMED TO, AND DID, COLLECTIVELY
NEGOTIATE HIGHER FEES**

12. In an attempt to prevent payors from decreasing reimbursement rates, in late 1996 several competing physicians founded SSY to negotiate collectively their payor contracts. These physicians did not, however, want to combine or integrate their practices. To assure prospective members that joining SSY would not affect any doctor’s ability to operate his or her individual practice, an SSY organizational document states, “[a]lthough your employees will be paid through the PLLC, you will retain management control of your own office including personnel, and all day to day operations as you currently control them.” That same document goes on to assure, “[a]lthough collections will be done on a centralized basis the actual billing of

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your services will be done through your own office and under your own control to ensure that each speciality maintains the knowledge necessary to bill using the CPT codes for their individual speciality services.” The cost of joining SSY was addressed in another organizational document, which states, “[n]et costs may well be insignificant if the organization enables us to improve our reimbursement rates by even a few points on the relative value scale.”

13. SSY’s operating agreement was drafted to create the appearance that SSY was operating as an integrated single entity, despite the reality that each member physician retained control of his or her individual practice. The operating agreement states, “all files of patients serviced or treated by or on behalf of the Company [SSY] shall remain the property of the Member which provides such services.” It also says, “each Member which is a corporation or who employs physician employees shall have the sole responsibility for paying its physician employees who render professional medical services on behalf of the Company. No physician employee of a Member shall be permitted to look to the Company for payment for services rendered.” The operating agreement’s system allocated income and expenses so that each member’s income was independent of the income earned by SSY or any of its individual members.

14. SSY’s first task after its formation was to implement its plan to collectively negotiate contracts with payors. It solicited fee information from its members saying, “we need to know as much as we can about your fees.”

15. SSY then provided its members with instructions on dealing with third party payers, telling them not to sign any new contracts or renew any existing contracts. In the summer of 1996, SSY instructed each individual physician or member of a medical group practice, including Respondents Cascade Surgical and Yakima Surgical, to send a form letter to payors, which states in part,

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I have joined a group practice, Surgical Specialists of Yakima, PLLC, and will be practicing totally as a member of that group effective October 1, 1996. This will require negotiation of a new contract for covered services as of that date. This should be negotiated through the representatives of Surgical Specialists of Yakima, PLLC.

Please accept this letter as notification of my resignation from our current existing contract effective October 1, 1996.

16. Since its formation, SSY has acted as the exclusive negotiator for its members, including Respondents Cascade Surgical and Yakima Surgical. For example, in 1999, when a payor approached some of SSY's doctors individually, SSY's clinic coordinator "warned" that if it continued to approach member doctors individually, SSY and its members would terminate their dealings with it.

17. All SSY negotiations with payors have followed the same pattern: SSY demands price increases of as much as 50 percent, and, when a payor balks, SSY's members, including Respondents Cascade Surgical and Yakima Surgical, following instructions from SSY's executive committee, then send form letters to their patients. For example, a letter that was sent to patients in July 2001 states:

Your physician _____ is a member of a larger group, Surgical Specialists of Yakima, PLLC. In April 2001 we requested that Premera Blue Cross renegotiate the terms of our contract which have been in effect since August 1999. They have declined to negotiate with us and our contract with Premera Blue Cross will terminate August 1, 2001.

We encourage you to contact your employer or Premera Blue Cross for the specific details of your policy and whether or not Premera will continue to pay benefits to non-participating physicians. If they do, then your out of pocket expense may be higher because you will be responsible for

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the difference between Premera's payment and the billed amount.

Whether we are participants in their network or not we are always willing to provide medical care for you and your family.

Please call any of our offices with any questions or concerns.

18. When such a letter fails to change a payor's stance, SSY then follows through on its threat and departicipates. In fact, during its existence SSY has, at least once, departicipated from contracts with the three largest commercial payors in the Yakima, Washington area.

19. A large share of the physicians who specialize in general surgery in the Yakima, Washington area are members of SSY, giving it substantial bargaining power with payors, with the result that payors have repeatedly acceded to Respondent SSY's demands for higher fees for its members than those members individually could have negotiated.

20. Through Respondent SSY's negotiations with payors for physician services at collectively agreed-upon terms, Respondent SSY's physician members, including Respondents Cascade Surgical and Yakima Surgical, have successfully contracted for the highest prices in the state for surgical codes, with conversion factors for surgical codes that are substantially higher than the conversion factors other physicians in the Yakima, Washington area receive for surgical codes.

**RESPONDENTS HAVE ENGAGED IN RESTRAINTS OF
TRADE**

21. Respondents have acted to restrain competition by, among other things:

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- a. facilitating, negotiating, entering into, and implementing agreements among the members of SSY on price and other competitively significant terms;
- b. refusing to deal with payors except on collectively agreed-upon terms; and
- c. negotiating uniform prices and other competitively significant terms in payor contracts for SSY's members.

**THERE ARE NO SIGNIFICANT EFFICIENCIES IN
RESPONDENTS' CONDUCT**

22. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

**RESPONDENTS' ACTIONS HAVE HAD SUBSTANTIAL
ANTICOMPETITIVE EFFECTS**

23. Respondents' actions described in Paragraphs 12 through 20 of this Complaint have had, or tend to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Yakima, Washington area in the following ways, among others:

- a. price and other forms of competition among Respondents Cascade Surgical and Yakima Surgical and other members of SSY were unreasonably restrained;
- b. prices for physician services were increased; and
- c. health plans, employers, and individual consumers were deprived of the benefits of competition among physicians.

24. The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of

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Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fourteenth day of November, 2003, issues its Complaint against Respondents SSY, Cascade Surgical and Yakima Surgical.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of Surgical Specialists of Yakima, P.L.L.C. (“SSY”), Cascade Surgical Partners, Inc., P.S. (“Cascade Surgical”), and Yakima Surgical Associates, Inc., P.S. (“Yakima Surgical”), hereinafter sometimes referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of the draft of Complaint that the counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

Decision and Order

1. Respondent SSY is a for-profit professional limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 307 South 12th Avenue, Yakima, WA 98902.
2. Respondent Cascade Surgical is a for-profit professional service corporation, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 3003 Tieton Drive, Yakima, WA 98902.
3. Respondent Yakima Surgical is a for-profit professional service corporation, organized, existing, and doing business under and by virtue of the laws of the State of Washington, with its principal address at 111 South 11th Avenue, Yakima, WA 98902.
4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent SSY” means Surgical Specialists of Yakima, P.L.L.C., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by SSY, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Respondent Cascade Surgical” means Cascade Surgical Partners, Inc., P.S., its officers, directors, employees, agents, representatives, successors, and assigns; and the

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subsidiaries, divisions, groups, and affiliates controlled by Respondent Cascade Surgical, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

- C. “Respondent Yakima Surgical” means Yakima Surgical Associates, Inc., P.S., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Respondent Yakima Surgical, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- D. “Respondents” means Respondent SSY, Respondent Cascade Surgical, and Respondent Yakima Surgical.
- E. “ Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- F. “ Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- G. “Payor” means any person that pays, or arranges for the payment, for all or any part of any physician services or hospital services for itself or for any other person. Payor includes any person that develops, leases, or sells access to networks of physicians or hospitals.
- H. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

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- I. “ Physician” means a doctor of allopathic medicine (“M.D.”), a doctor of osteopathic medicine (“D.O.”), a doctor of chiropractic medicine (“D.C.”), or a doctor of podiatric medicine (“D.P.M.”).
- J. “ Preexisting contract” means a contract that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by Respondent SSY, pursuant to Paragraph IV.A.4 of this Order, of such payor’s right to terminate such contract.
- K. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- L. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 - 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- M. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate jointly to control costs and improve quality

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by managing the provision of physician services, such as risk-sharing involving:

- a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

Decision and Order

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 - 1. to negotiate on behalf of any physician with any payor,
 - 2. to deal, refuse to deal, or threaten to refuse to deal with any payor,
 - 3. regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms, or
 - 4. not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent SSY;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal;
- C. Attempting to engage in any action prohibited by Paragraph II.A or II.B, above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.

PROVIDED, HOWEVER, that nothing in this Paragraph II shall prohibit any agreement involving or conduct by Respondent SSY, subject to the provisions of Paragraph III below, or by Respondents Cascade Surgical and Yakima Surgical, that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or

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qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice.

III.

IT IS FURTHER ORDERED that:

- A. Respondent SSY shall, pursuant to each purported qualified risk-sharing joint arrangement or purported qualified clinically-integrated joint arrangement (“Arrangement”), for five (5) years from the date this Order becomes final, notify the Secretary of the Commission in writing (“Notification”) at least sixty (60) days prior to:
1. Participating in, organizing, or facilitating any discussion or understanding with or among any physicians in such Arrangement relating to price or other terms or conditions of dealing with any payor; or
 2. Contacting a payor, pursuant to an Arrangement to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any payor, on behalf of any physician in such Arrangement.

PROVIDED, HOWEVER, that Notification required by this Paragraph III.A is not required for negotiations or agreements with subsequent payors pursuant to any Arrangement for which this Notification was given; and

- B. Respondent SSY shall include the following information in this Notification:
1. for each physician participant, his or her name, address, telephone number, medical specialty, medical practice group, if applicable, and the name of each hospital where he or she has privileges;

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2. a description of the Arrangement, its purpose, function, and area of operation;
3. a description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;
4. an explanation of the relationship of any agreement on prices, or contract terms related to price, to furthering the integration and achieving the efficiencies of the Arrangement;
5. a description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities; and
6. all studies, analyses, and reports, which were prepared for the purpose of evaluating or analyzing competition for physician services in any relevant market, including, but not limited to, Respondent SSY's, any physician's, or any medical practice group's market share of physician services in any relevant market.

PROVIDED, HOWEVER that the expiration of the waiting period described herein shall not be construed as a determination by the Commission, or its staff, that a violation of the law, or of this Order, may not have occurred. In addition, the absence of notice to SSY that the Arrangement has been rejected shall not be construed as a determination by the Commission, or its staff, that the Arrangement has been approved. Provided further that, receipt by the Commission from SSY of any Notification of an Arrangement is not to be construed as a determination by the Commission that any such Arrangement does or does not violate this Order or any law enforced by the Commission.

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IV.

IT IS FURTHER ORDERED that Respondent SSY shall:

- A. Within thirty (30) days after the date on which this Order becomes final:
1. send by first-class mail, with delivery confirmation, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to each physician who participates, or has participated, in Respondent SSY;
 2. send by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to each officer, director, manager, and employee of Respondent SSY;
 3. send by first-class mail, return receipt requested, copies of this Order, the Complaint, the Analysis of the Proposed Order to Aid Public Comment, and the notice specified in Appendix A to this Order to the chief executive officer of each payor Respondent SSY has a record of having been in contact with since January 1, 2001, regarding contracting for the provision of physician services; and
 4. terminate, without penalty or charge, and in compliance with any applicable laws, any preexisting contract with any payor for the provision of physician services, at the earlier of: (a) receipt by Respondent SSY of a written request from a payor to terminate such contract, or (b) the earliest termination or renewal date (including any automatic renewal date) of such contract. Provided, however, a preexisting contract may extend beyond any such termination or renewal date no later than one year after the date on which the Order becomes final, if prior to such termination or renewal date, (i) the payor submits to Respondent SSY a written request to extend such contract to a specific date no later than one year after the Order

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becomes final, and (ii) Respondent SSY has determined not to exercise any right to terminate. Provided further, that any payor making such request to extend a contract retains the right, pursuant to part (a) of this paragraph, to terminate the contract at any time.

- B. Within 180 days after the date on which the Order becomes final:
1. revoke the membership in Respondent SSY, without penalty or negative financial consequences, of either Respondent Cascade Surgical or Respondent Yakima Surgical (“Revoked Entity”), including the memberships of the individual physician members of that Revoked Entity; and
 2. cease and desist from all financial and contractual relationships with the Revoked Entity, excluding coordination of clinical activities, including, but not limited to, any arrangement under which Respondent SSY acts or would act as an agent or otherwise on behalf of the Revoked Entity, in dealing with payors regarding contracts under which the Revoked Entity would be compensated for the provision of physician services; provided, however, that Respondent SSY may engage in those activities that are required to comply with the terms of this Order, including, but not limited to Paragraph IV.B.1.
- C. For five (5) years after the date on which this Order becomes final:
1. cease and desist from admitting as a member and having any financial relationship or contractual relationship with any individual doctor, who currently is a member of the Revoked Entity;
 2. notify the Secretary of the Commission in writing at least sixty (60) days prior to admitting into membership any physician or medical group practice, who during the prior

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year, provided physician services in Yakima County, Washington;

3. distribute by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to:
 - a. each physician who begins participating in Respondent SSY for the provision of physician services, and who did not previously receive a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment, within thirty (30) days of the time that such participation begins;
 - b. each payor who contracts with Respondent SSY for the provision of physician services, who did not previously receive a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment from Respondent SSY, within thirty (30) days of the time that such payor enters into such contract; and
 - c. each person who becomes an officer, director, manager, or employee of Respondent SSY, and who did not previously receive a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment from Respondent SSY, within thirty (30) days of the time that he or she assumes such status with Respondent SSY; and
4. annually publish in an official annual report or newsletter sent to all physicians who participate in Respondent SSY a copy of the Analysis of the Proposed Order to Aid Public Comment, published in conjunction with this Order and the accompanying Complaint, with such prominence as is given to regularly featured articles; and
5. notify the Commission at least thirty (30) days prior to any proposed change in Respondent SSY, such as dissolution,

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assignment, sale resulting in the emergence of a successor, the formation of a medical group practice, the creation or dissolution of subsidiaries or any other change in Respondent SSY that may affect compliance obligations arising out of this Order.

- D. For ten (10) years after the date on which the Order becomes final, cease and desist from readmitting the Revoked Entity as a member.

V.

IT IS FURTHER ORDERED that Respondent Cascade Surgical and Respondent Yakima Surgical shall:

- A. Within thirty (30) days after the date on which the Order becomes final, send by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to each officer, director, manager, and employee of that Respondent;
- B. For five (5) years after the date on which this Order becomes final, distribute by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to each person who becomes an officer, director, manager, or employee of that Respondent, and who did not previously receive a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment, within thirty (30) days of the time that he or she assumes such status with such Respondent;
- C. If it is the Revoked Entity, for five (5) years after the date on which this Order becomes final, distribute by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment to:

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1. each physician who begins participating in the Revoked Entity for the provision of physician services, and who did not previously receive a copy of this Order, the Complaint, and the Analysis of the Proposed Order to Aid Public Comment from Respondent SSY, within thirty (30) days of the time that such participation begins; and
 2. each payor who contracts with the Revoked Entity for the provision of physician services, and who did not contract with Respondent SSY at the date that this Order became final, within thirty (30) days of the time that such payor enters into such contract;
- D. If it is not the Revoked Entity, for three (3) years after the date on which this Order becomes final, cease and desist from admitting into its practice any physician who participated in the practice of the Revoked Entity at the date on which this Order becomes final.

VI.

IT IS FURTHER ORDERED that Respondents shall file verified written reports within sixty (60) days after the date on which this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth:

- A. In detail, the manner and form in which Respondents have complied and are complying with this Order;
- B. The name, address, and telephone number of each payor with which Respondents have had any contact; and
- C. Copies of the delivery confirmations and signed return receipts required by Paragraphs IV. and V.

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VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under their control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to such Respondents, and in the presence of counsel, and without restraint or interference from it, to interview such Respondents or employees of such Respondents.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate on November 14, 2023.

By the Commission.

Decision and Order

Appendix A

[letterhead of Surgical Specialists of Yakima, P.L.L.C.]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against Surgical Specialists of Yakima ("SSY"), and others.

Pursuant to Paragraph IV.A.6. of the enclosed consent order, SSY must allow you to terminate, upon your written request, without any penalty or charge, any contracts with SSY that were in effect prior to your receipt of this letter.

Paragraph IV.A.6. of the consent order also provides that, if you do not terminate a contract, the contract will terminate on its earliest termination or renewal date (including any automatic renewal date). However, at your request, the contract may be extended to a date no later than [appropriate date to be filled in by SSY], but only if SSY waives its right to terminate the contract. If you choose to extend the term of the contract, you may later terminate the contract at any time.

Any request either to terminate or to extend the contract should be made in writing, and sent to me at the following address:
[address].

Sincerely,

[CEO of SSY]

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Surgical Specialists of Yakima, P.L.L.C. (SSY), and two general surgery groups – Cascade Surgical Partners, Inc., P.S. (CSP) and Yakima Surgical Associates, Inc., P.S. (YSA) – that are members of SSY. The agreement settles charges that these parties violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by orchestrating and implementing agreements among members of SSY to fix prices and other terms on which they would deal with health plans, agreements enforced by SSY’s members’ refusal to deal with such purchasers except on collectively-determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations of the complaint are summarized below.

SSY was organized in 1996 by several independent medical practices. Those medical practices, which became “members” of SSY, were and are separate and independent in all material

Analysis

respects, are not subject to the control of SSY, have not unified their economic interests and incentives through SSY, and are not significantly integrated (either clinically or financially). SSY's activities on behalf of its members constitute the combined action of those members, and not unilateral action by SSY. SSY presently has 24 physician members that practice in five specialties, ENT, OB/GYN, Ophthalmology, Plastic Surgery, and General Surgery. SSY represents 90 percent of all physicians practicing general surgery in and around Yakima, Washington, which is located in south-central Washington.

According to the complaint, SSY members refuse to negotiate or contract with health plans on an individual basis. Instead, all negotiations are conducted by SSY, and SSY's members accept only those contracts deemed acceptable by SSY. In accordance with this model, Respondents have orchestrated collective agreements on fees and other terms of dealing with health plans, have carried out collective negotiations with several health plans, and have refused and threatened to refuse to deal with health plans who resisted Respondents' desired terms.

The complaint alleges that Respondents have succeeded in forcing health plans to raise fees paid to SSY members and thereby raised the cost of medical care in the Yakima area. As a result of the challenged actions of Respondents, SSY members receive the highest fees for surgical services in Washington. By orchestrating agreements among SSY members to deal only on collectively-determined price and other terms, Respondents have violated Section 5 of the FTC Act.

The Proposed Consent Order

The proposed order is designed to remedy the illegal conduct charged in the complaint and prevent its recurrence. It is similar to many previous consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise fees they receive from health plans, but with one additional provision. In addition to the core prohibitions, the

Analysis

proposed order in this matter requires that SSY revoke the membership of either CSP or YSA. Such structural relief is not routinely imposed but is necessary in this case to reduce SSY's market power in general surgery.

The proposed order's specific provisions are as follows:

Paragraph II.A prohibits the Respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, to refuse to deal, or to threaten to refuse to deal with payors; (3) regarding the terms of dealing with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving the Respondent SSY.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the Respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to deal with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B; and Paragraph II.D proscribes inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

As in other orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. Respondents would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians, whether a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement."

As defined in the proposed order, a "qualified risk-sharing joint arrangement" possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the physician participants jointly to control costs and improve quality by managing the provision of services.

Analysis

Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A “qualified clinically-integrated joint arrangement” on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraph IV, which applies only to SSY, solves the market power issue by requiring SSY to revoke the membership of either CSP or YSA. It also requires SSY to distribute the complaint and order to all physicians who have participated in SSY, and to payors that negotiated or indicated an interest in negotiating contracts with SSY, and requires SSY to terminate, at any payor’s request and without penalty, its current contracts with respect to providing physician services. Finally, SSY is prohibited from readmitting any physician from the revoked entity for five years and from readmitting the revoked entity for 10 years.

Paragraph V, which applies only to CSP and YSA, requires them to distribute the complaint and order to all physicians who have participated in their activities and to any physicians who become involved with either CSP or YSA in the future.

Paragraphs III, VI, and VII of the proposed order impose various obligations on Respondents to report or provide access to information to the Commission to facilitate monitoring Respondents’ compliance with the order.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

NEW HAMPSHIRE MOTOR TRANSPORT ASSOCIATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4102; File No. 0210115

Complaint, December 4, 2003--Decision, December 4, 2003

This consent order, among other things, prohibits Respondent New Hampshire Motor Transport Association – an association with, as members, approximately 400 firms primarily engaged in the trucking industry, including approximately 19 household goods movers that conduct business within the State of New Hampshire – from filing tariffs that contain rules mandating automatic price increases. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers' agreement to include such rules in their intrastate tariffs. In addition, the order requires the respondent to cancel all tariffs it has filed that contain rules concerning automatic rate increases; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send a letter explaining the terms of the order to its members engaged in moving household goods.

Participants

For the Commission: *Dana Abrahamsen, Patrick J. Roach, Richard B. Dagen, John Howell and Mary T. Coleman.*

For the Respondent: *Daniel Luker, Prety, Flaherty, Beliveau & Haley.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that New Hampshire Motor Transport Association (hereinafter sometimes referred to as “respondent” or “NHMTA”), an association, has violated and is now violating the provisions of Section 5 of said Act, and it appearing to the Commission that a

Complaint

proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

NATURE OF THE CASE

This matter concerns horizontal agreements among competing household goods movers that, through respondent, file tariffs for intrastate moving services in New Hampshire. The tariffs contain rules that state that participating movers must increase their rates to consumers for moving services rendered during the peak moving season. Through these tariff rules, the participating movers engage in a horizontal agreement affecting prices for their services.

RESPONDENT AND ITS MEMBERS

PARAGRAPH 1. Respondent New Hampshire Motor Transport Association is an association organized, existing, and doing business under and by virtue of the laws of the State of New Hampshire, with its office and principal place of business located at 13 West Street, Concord, New Hampshire 03301.

PARAGRAPH 2. Respondent is an association organized for and serving its members' interests, including their economic interests, by promoting, fostering and advancing the household goods moving industry in the State of New Hampshire. One of the functions of respondent is the initiation, preparation, development, dissemination and filing with the New Hampshire Department of Safety's Bureau of Common Carriers of tariffs and supplements thereto on behalf of and as agent for its members that are engaged in the transportation of household goods. Said tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services, including, among other things, transporting bulky articles; packing boxes and crates; and extra charges for elevator, stair, and long distance carrying of items. (For purposes of this complaint, the term "tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of

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New Hampshire, including updates, revisions, and/or amendments, including general rules and regulations.)

PARAGRAPH 3. Pursuant to New Hampshire state law, each household goods mover is required to file a tariff with the New Hampshire Bureau of Common Carriers containing the carrier's rates, fares, or charges for the intrastate transportation of household goods. By New Hampshire law, a household goods mover is not permitted to charge a rate, fare, or charge different from those contained in its tariff or supplements thereto once the Bureau of Common Carriers has accepted it.

PARAGRAPH 4. Members of respondent are engaged, among other things, in the business of providing transportation and other services for compensation as household goods movers between points within the State of New Hampshire. Except to the extent that competition has been restrained as herein alleged, some members of respondent have been and are now in competition among themselves and with other household goods movers.

PARAGRAPH 5. The membership of NHMTA consists of approximately 400 members of which 19 members are household goods movers that conduct business within the State of New Hampshire. Those 19 NHMTA members receive compensation for intrastate and local moves. Members of NHMTA are entitled to and do, among other things, vote for and elect the directors of the association. The control, direction, and management of NHMTA are vested in the directors, who elect a President, a Vice President, and a Treasurer to carry on the day-to-day administration and management of NHMTA.

JURISDICTION

PARAGRAPH 6. The acts and practices of respondent set forth in Paragraph 7 have been and are now in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, and respondent is subject to the

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jurisdiction of the Federal Trade Commission. Among other things, the aforesaid acts and practices:

- (A) Affect the flow of substantial sums of money from the federal government, business, and other private parties to the respondent's members for rendering transportation services, which money flows across state lines;
- (B) Affect the purchase and use of equipment and other goods and services by respondent's members that are shipped in interstate commerce;
- (C) Include the use of the United States mail and other instruments of interstate commerce in furthering the agreements described below; and
- (D) Are supported by the receipt of dues and fees for publications and services from out-of-state members and others.

THE CHALLENGED CONDUCT

PARAGRAPH 7. For many years and continuing up to and including the date of the filing of this complaint, respondent, its members, its officers and directors, and others have agreed to engage, and have engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is, was, or may be to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the intrastate New Hampshire household goods moving industry.

Pursuant to, and in furtherance of, said agreement and concert of action, respondent, its members and others have engaged and continue to engage in the following acts, policies, and practices, among others:

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(A) Participating in and continuing to participate in tariffs that contain rules whereby carriers agree to institute automatic changes to rates on file for said carriers;

(B) Initiating, preparing, developing, disseminating, and taking other actions to establish and maintain tariff rules that have the purpose or effect of fixing, establishing, stabilizing or otherwise tampering with rates and charges for the transportation of household goods between points within the State of New Hampshire;

(C) Filing tariffs with the New Hampshire Bureau of Common Carriers that contain rules that institute automatic changes to rates of carriers with tariffs on file with the Department of Safety; and

(D) Initiating, organizing, coordinating, and conducting meetings or providing a forum for any discussion or agreement among competing carriers concerning or affecting tariffs that contain rules whereby carriers agree to institute automatic changes to rates on file for carriers.

PARAGRAPH 8. The acts and practices of respondent, its members and others, as alleged in Paragraph 7, have had and are now having the effects, among others, of:

(A) Raising, fixing, stabilizing, pegging, maintaining, or otherwise interfering or tampering with the prices of household goods moves;

(B) Restricting, restraining, hindering, preventing, or frustrating price competition in the household goods moving industry; and

(C) Depriving consumers of the benefits of competition.

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THE VIOLATION CHARGED

PARAGRAPH 9. The acts, policies and practices of respondent, its members and others, as herein alleged, were and are to the prejudice and injury of the public and constituted and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fourth day of December, 2003, issues its complaint against NHMTA.

By the Commission, Commissioner Harbour not participating.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of New Hampshire Motor Transport Association (“NHMTA”), hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent New Hampshire Motor Transport Association is a not-for-profit association, organized and existing under the laws of the State of New Hampshire with its principal office and

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place of business at 13 West Street, Concord, New Hampshire 03301.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED, that for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "NHMTA" means New Hampshire Motor Transport Association, its officers, directors, executive board, committees, representatives, agents, employees, successors and assigns;
- B. "Carrier" means a common or contract carrier of property by motor vehicle within the State of New Hampshire subject to regulation as a "Household Goods Carrier" under NH RSA 375-A or any successor statute;
- C. "Intrastate transportation" means the pickup or receipt, transportation and delivery of property hauled between points within the State of New Hampshire for compensation by a carrier authorized by the New Hampshire Bureau of Common Carriers ("NHBCC") to engage therein;
- D. "Member" means any carrier that pays dues or belongs to NHMTA or to any successor corporation;
- E. "Tariff" means the publication, including but not limited to those currently required by NH RSA 375-A, stating the rates of a carrier for the transportation of property between points within the State of New Hampshire, including

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updates, revisions, and/or amendments, and any corresponding general rules and regulations;

- F. "Rate" means a charge, payment or price fixed according to a ratio, scale or standard for direct or indirect transportation service;
- G. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

II.

IT IS FURTHER ORDERED that Respondent shall forthwith cease and desist from entering into and within 120 days after service upon it of this Order cease and desist from maintaining, directly or indirectly, any contract, agreement, understanding, plan, program, or combination, by or among carriers, to fix, stabilize, raise, maintain or otherwise set the rates charged by two or more carriers in connection with the intrastate transportation of property or related services, goods or equipment, including but not limited to:

1. Preparing, developing, disseminating or filing a proposed or existing tariff containing rules instituting automatic changes to rates charged by two or more carriers;
2. Inviting, coordinating or providing a forum for any discussion or agreement between or among competing carriers concerning automatic rate changes for the intrastate transportation of property or related services, goods or equipment;
3. Providing information to any carrier about rate changes considered or made by any other carrier prior to the time at which such rate change becomes a matter of public record with the NHBCC;

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4. Suggesting, urging, encouraging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, including automatic rate adjustments, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided; and
5. Maintaining any rate or tariff committee or other entity to consider, pass upon, compile, monitor, assist in the circulation of, or discuss rules pertaining to automatic rate adjustments with respect to carriers.

III.

IT IS FURTHER ORDERED that Respondent shall, within 120 days after service upon it of this Order:

1. Cancel all tariff provisions on file with the NHBCC that institute automatic changes to rates charged by two or more carriers and take such action as may be necessary to effectuate cancellation and withdrawal of such provisions;
2. Terminate any previously-executed powers of attorney and rate and tariff service agreements, between NHMTA and any carrier utilizing its services, authorizing the publication and/or filing of tariffs containing rules regarding automatic rate increases within the State of New Hampshire;
3. Cancel any provisions of NHMTA's articles of incorporation, by-laws and procedures and any other rules, opinions, resolutions, contracts or statements of policy that have the purpose or effect of permitting, announcing, stating, explaining or agreeing to any business practice enjoined by the terms of this Order; and
4. Amend NHMTA's by-laws to require members engaged in the transportation of household goods to observe the provisions of the Order as a condition of membership in NHMTA.

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IV.

IT IS FURTHER ORDERED that, within fifteen (15) days after service upon it of this Order, Respondent shall mail or deliver a copy of this Order, under cover of the letter attached hereto as "Appendix," to each member of Respondent that currently files its tariff through NHMTA, and for a period of three (3) years from the date of service of this Order, to each new member engaged in the transportation of household goods within ten (10) days of such member's acceptance by Respondent.

V.

IT IS FURTHER ORDERED that Respondent notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment or sale resulting in the emergence of a successor entity, or any other proposed change in the structure or ownership of the Respondent, which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that Respondent shall file a written report within six (6) months of the date of service of this Order, and annually on the anniversary date of the original report for each of the five (5) years thereafter, and at such other times as the Commission may require by written notice to Respondent, setting forth in detail the manner and form in which Respondent has complied with this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on December 4, 2023.

By the Commission, Commissioner Harbour not participating.

Decision and Order

APPENDIX

(Letterhead of the New Hampshire Motor Transport Association)

Dear Tariff Member:

The Federal Trade Commission has ordered the New Hampshire Motor Transport Association (NHMTA) to cease and desist from assisting with the filing of tariffs that contain rules calling for automatic rate increases and, in particular, the “seasonal adjustment” provision of Rule 28 of the existing tariff. A copy of the Commission’s Decision and Order is enclosed.

The terms of the Order itself are controlling, but its essential provisions are as follows:

(1) NHMTA is prohibited from filing any tariffs that have rules that call for tariff members to automatically increase their rates. Each member carrier must independently set its own rates for transportation of property or related services, goods or equipment between points within the State of New Hampshire. Tariff members may still use NHMTA as a tariff publishing agent provided that the tariff does not contain any rules calling for automatic rate increases such as the “seasonal adjustment” rule.

(2) NHMTA is prohibited from providing a forum for its tariff members for the purpose of discussing rules concerning automatic rate increases.

(3) NHMTA is prohibited from urging, suggesting, encouraging or attempting to influence in any way the rates members charge for their intrastate transportation services, including influencing members to make automatic rate adjustments. NHMTA may not provide non-public information to any carrier about rate changes ordered by another carrier.

(4) NHMTA is prohibited from maintaining any rate or tariff committee which discusses or formulates rules pertaining to

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automatic rate increases.

(5) NHMTA has 120 days to make sure that all tariffs and tariff supplements on file at the New Hampshire Bureau of Common Carriers which were filed by the NHMTA contain no rules calling for automatic rate increases and, in particular, the “seasonal adjustment” rule.

(6) NHMTA is required to amend its by-laws to require its tariff members to observe the provisions of the Order as a condition of membership in NHMTA.

Sincerely yours,

[appropriate NHMTA officer]

Enclosure

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with New Hampshire Motor Transport Association (“NHMTA” or “Respondent”). The Agreement is for settlement purposes only and does not constitute an admission by NHMTA that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

I. The Commission’s Complaint

The proposed Complaint alleges that Respondent New Hampshire Motor Transport Association, a corporation, has violated and is now violating Section 5 of the Federal Trade Commission Act. Specifically, the proposed Complaint alleges that Respondent has agreed to engage, and has engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the State of New Hampshire.

Respondent is an association organized for and serving its members, which are approximately 400 firms primarily engaged in the trucking industry, of which approximately 19 members are household goods movers that conduct business within the State of New Hampshire. One of the functions of Respondent is preparing, and filing with the New Hampshire Department of Safety’s Bureau of Common Carriers, tariffs and supplements on behalf of members engaged in moving household goods. These tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services.

The proposed Complaint alleges that Respondent is engaged in initiating, preparing, developing, disseminating, and taking other actions to establish and maintain tariff rules which have the

Analysis

purpose or effect of fixing, establishing or stabilizing rates for the transportation of household goods in the State of New Hampshire. The proposed Complaint further alleges that Respondent files with the New Hampshire Bureau of Common Carriers tariffs containing rules that institute automatic increases to carriers' rates.

The proposed Complaint further alleges that Respondent's conduct is anticompetitive because it has the effect of raising, fixing, and stabilizing the prices of household goods moves. The acts of Respondent also have the effect of depriving consumers of the benefits of competition.

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the conduct principally by requiring Respondent to cease and desist from its practice of filing tariffs containing rules that call for automatic increases in movers' intrastate rates.

Paragraph II of the proposed Order bars Respondent from filing a tariff that contains rules mandating automatic price increases. This provision will terminate Respondent's current practice of filing tariffs that contain such rules that are the product of an agreement among movers in the State of New Hampshire. This paragraph also prohibits Respondent from engaging in activities such as exchanges of information that would facilitate member movers' agreement to include such rules in their intrastate tariffs. For example, the order bars Respondent from providing certain non-public information to member carriers.¹

Paragraph III of the proposed Order requires Respondent to cancel all tariffs that it has filed that contain rules concerning

¹ A state statute requires carriers to keep their tariffs "open to public inspection." N.H. Rev. Stat. § 375-A:9.

Analysis

automatic rate increases. This provision will ensure that the intrastate tariffs containing such rules now on file in the State of New Hampshire will no longer be in force, allowing for future individual mover tariffs. Paragraph III of the proposed Order also requires Respondent to cancel any provisions in its governing documents that permit it to engage in activities barred by the Order.

Paragraph IV of the proposed Order requires Respondent to send a letter explaining the terms of the Order to its members engaged in moving household goods. This will make clear to members that they can no longer engage in activities prohibited by the Order.

Paragraphs V and VI of the proposed Order require Respondent to inform the Commission of any change in Respondent that could affect compliance with the Order and to file compliance reports with the Commission for a number of years. Paragraph VII of the proposed Order states that the Order will terminate in 20 years.

III. Opportunity for Modification of the Order

Should the Commission issue a final Order in this matter, Respondent can seek to modify that Order to permit it to engage in collective action regarding prices if it can demonstrate that the “state action” defense would apply to its conduct.² The Commission has recently explained in detail the factors it would consider in determining whether the state action defense is met.³

² 16 C.F.R. § 2.51.

³ See Analysis of Proposed Consent Order to Aid Public Comment in: *Indiana Household Movers and Warehousemen, Inc.* (Mar. 18, 2003) available at <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf>; *Iowa Movers and Warehousemen’s Association* (Aug. 1, 2003) available at <http://www.ftc.gov/os/2003/08/imwaanalysis.htm>;

Analysis

At present, Respondent would not be able to establish that its conduct is covered by the state action defense because the State of New Hampshire does not actively supervise the tariffs filed by Respondent.

IV. Opportunity for Public Comment

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the proposed Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or to modify their terms in any way.

and *Minnesota Transport Services Association* (Aug. 1, 2003)
available at <http://www.ftc.gov/os/2003/08/mtsaanalysis.htm>.

Complaint

IN THE MATTER OF

ALABAMA TRUCKING ASSOCIATION, INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket 9307; File No. 0210115**Complaint, July 8, 2003--Decision, July 8, 2003*

This consent order, among other things, prohibits Respondent Alabama Trucking Association, Inc. – an association with, as members, approximately 80 household goods movers that conduct business within the State of Alabama – from filing tariffs that contain collective intrastate rates. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. In addition, the order prohibits the respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases. The order also requires the respondent to cancel all tariffs it has filed that contain intrastate collective rates; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send its members a letter explaining the terms of the order.

Participants

For the Commission: *Dana Abrahamsen, Patrick J. Roach, Richard B. Dagen, John Howell and Mary T. Coleman.*

For the Respondent: *James Sizemore.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Alabama Trucking Association, Inc. (hereinafter sometimes referred to as “respondent” or “ATA”), a corporation, has violated and is now violating the provisions of Section 5 of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

Complaint

NATURE OF THE CASE

This matter concerns horizontal agreements among competing household goods movers that, through respondent, file tariffs for intrastate moving services in Alabama. The tariffs contain collective rates that participating movers charge consumers for moving services. Through these tariffs, the participating movers engage in a horizontal agreement to fix prices for their services.

RESPONDENT AND ITS MEMBERS

PARAGRAPH 1. Respondent Alabama Trucking Association, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Alabama, with its office and principal place of business located at 660 Adams Avenue, Montgomery, Alabama 36104.

PARAGRAPH 2. Respondent is an association organized for and serving its members' interests, including their economic interests, by promoting, fostering, and advancing the household goods moving industry in the State of Alabama. One of the primary functions of respondent is the initiation, preparation, development, dissemination, and filing with the Alabama Public Service Commission of tariffs and supplements thereto on behalf of and as agent for its members. Said tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services, including, among other things, transporting bulky articles; packing cartons and crates; and extra charges for elevator, stair, and long distance carrying of items. (For purposes of this complaint, the term "tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Alabama, including updates, revisions, and/or amendments, including general rules and regulations.)

PARAGRAPH 3. Pursuant to Alabama state law, each household goods mover is required to file a tariff with the Alabama Public Service Commission containing the carrier's

Complaint

rates, fares, or charges for the intrastate transportation of household goods. By Alabama law, a household goods mover is not permitted to charge a rate, fare, or charge different from those contained in its tariff or supplements thereto once the Alabama Public Service Commission has accepted it.

PARAGRAPH 4. Members of respondent are engaged, among other things, in the business of providing transportation and other services for compensation as household goods movers between points within the State of Alabama. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other household goods movers.

PARAGRAPH 5. The membership of ATA includes approximately 80 household goods movers that conduct business within the State of Alabama. ATA members receive compensation for intrastate and local moves. Members of ATA are entitled to and do, among other things, vote for and elect the officers and board members of the association, including the Chairman of the Board, the Vice Chairman of the Board, and the Treasurer.

JURISDICTION

PARAGRAPH 6. The acts and practices of respondent set forth in Paragraph 7 have been and are now in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, and respondent is subject to the jurisdiction of the Federal Trade Commission. Among other things, the aforesaid acts and practices:

- (A) Affect the flow of substantial sums of money from the federal government, business, and other private parties to the respondent's members for rendering transportation services, which money flows across state lines;

Complaint

(B) Affect the purchase and use of equipment and other goods and services by respondent's members that are shipped in interstate commerce;

(C) Include the use of the United States mail and other instruments of interstate commerce in furthering the agreements described below; and

(D) Are supported by the receipt of dues and fees for publications and services from out-of-state members and others.

THE CHALLENGED CONDUCT

PARAGRAPH 7. For many years and continuing up to and including the date of the filing of this complaint, respondent, its members, its officers and directors, and others have agreed to engage, and have engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is, was, or may be to unlawfully hinder, restrain, restrict, suppress, or eliminate competition among household goods movers in the intrastate Alabama household goods moving industry.

Pursuant to, and in furtherance of, said agreement and concert of action, respondent, its members and others have engaged and continue to engage in the following acts, policies, and practices, among others:

(A) Initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, with the purpose or effect of fixing, establishing, stabilizing or otherwise tampering with rates and charges for the transportation of household goods between points within the State of Alabama;

(B) Participating in and continuing to participate in the collectively set rates;

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(C) Filing collectively set rates with the Alabama Public Service Commission; and

(D) Initiating, organizing, coordinating, and conducting meetings or providing a forum for any discussion or agreement among competing carriers concerning or affecting rates charged or proposed to be charged for the intrastate transportation of household goods; or otherwise influencing its members to raise their rates, charge the same or uniform rates, or participate or continue to participate in the collectively set rates.

PARAGRAPH 8. The acts and practices of respondent, its members and others, as alleged in Paragraph 7, have had and are now having the effects, among others, of:

(A) Raising, fixing, stabilizing, pegging, maintaining, or otherwise interfering or tampering with the prices of household goods moves;

(B) Restricting, restraining, hindering, preventing, or frustrating price competition in the household goods moving industry; and

(C) Depriving consumers of the benefits of competition.

THE VIOLATION CHARGED

PARAGRAPH 9. The acts, policies and practices of respondent, its members and others, as herein alleged, were and are to the prejudice and injury of the public and constituted and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

Complaint

Notice

Notice is hereby given to the Respondent that the eighth day of October, 2003, at 10:00 a.m., or such later date as determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the FTC Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded to you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under § 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings and the right to appeal the initial decision to the Commission under § 3.52 of said Rules.

Complaint

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions, and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a Respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice of Contemplated Relief

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that respondent's conduct violated Section 5 of the Federal Trade Commission Act as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including but not limited to:

1. Requiring respondent to cease and desist from preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment.
2. Requiring respondent to cease and desist from providing information to any carrier about rate changes considered or

Complaint

made by any other carrier employing the publishing services of respondent prior to the time at which such rate changes become a matter of public record.

3. Requiring respondent to cease and desist from inviting, coordinating or providing a forum (including maintaining any rate or tariff committee) for any discussion or agreement between or among competing carriers concerning rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment.
4. Requiring respondent to cease and desist from suggesting, urging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided.
5. Requiring respondent to cease and desist from preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.
6. Requiring respondent to cancel all tariffs and any supplements thereto on file with the state that establish rates for transportation of property or related services, goods or equipment.
7. Requiring respondent to cancel those provisions of its articles of incorporation, by-laws and procedures, tariff service agreements and every other rule that has the purpose or effect of permitting, announcing, explaining or agreeing to any business practice enjoined by the terms of any order, and to amend its by-laws to require members to observe the provisions of any order.

Complaint

8. Requiring respondent to make public, in a manner likely to reach as many members as possible, the nature of the relief ordered by the Commission.
9. Such additional relief as is necessary to correct or remedy the violations alleged in the complaint.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighth day of July, 2003, issues its complaint against ATA.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having heretofore issued its Complaint charging the Alabama Trucking Association, Inc. (“ATA”), hereinafter sometimes referred to as “Respondent,” with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Respondent having been served with a copy of that Complaint, together with a Notice of Contemplated Relief; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with Commission Rule 3.25(c), 16 C.F.R. § 3.25(c); and

The Commission having thereafter considered the matter and thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 3.25(f), 16 C.F.R. § 3.25(f), the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Alabama Trucking Association, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Alabama, with its office and

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principal place of business located at 660 Adams Avenue, Montgomery, Alabama 36104.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "ATA" means the Alabama Trucking Association, Inc., its officers, executive board, committees, parents, representatives, agents, employees, successors and assigns;
- B. "Carrier" means a common carrier of property by motor vehicle;
- C. "Intrastate transportation" means the pickup or receipt, transportation and delivery of property hauled between points within the State of Alabama for compensation by a carrier authorized by the Alabama Public Service Commission to engage therein;
- D. "Member" means any carrier or other person that pays dues or belongs to ATA or to any successor corporation;
- E. "Tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Alabama, including updates, revisions, and/or amendments, including general rules and regulations;

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- F. "Rate" means a charge, payment or price fixed according to a ratio, scale or standard for direct or indirect transportation service;
- G. "Collective rates" means any rate or charge established under any contract, agreement, understanding, plan, program, combination or conspiracy between two or more competing carriers, or between any two or more carriers and Respondent; and
- H. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

II.

IT IS FURTHER ORDERED that Respondent, its successors and assigns, and its officers, agents, representatives, directors and employees, directly or through any corporation, subsidiary, division or other device, shall forthwith cease and desist from entering into and within 120 days after service upon it of this Order cease and desist from adhering to or maintaining, directly or indirectly, any contract, agreement, understanding, plan, program, combination or conspiracy to fix, stabilize, raise, maintain or otherwise interfere or tamper with the rates charged by two or more carriers for the intrastate transportation of property or related services, goods or equipment, including, but not limited to:

1. Knowingly preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment;
2. Providing information to any carrier about rate changes considered or made by any other carrier employing the publishing services of Respondent prior to the time at which such rate change becomes a matter of public record;

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3. Inviting, coordinating or providing a forum (including publication of an informational bulletin) for any discussion or agreement between or among competing carriers concerning rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment;
4. Suggesting, urging, encouraging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided;
5. Maintaining any rate or tariff committee or other entity to consider, pass upon or discuss intrastate rates or rate proposals; and
6. Preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.

III.

IT IS FURTHER ORDERED that Respondent shall, within 120 days after service upon it of this Order:

1. Cancel all tariffs and any supplements thereto on file with the Alabama Public Service Commission that establish rates for transportation of property or related services, goods or equipment by common carriers in the State of Alabama and take such action as may be necessary to effectuate cancellation and withdrawal;
2. Terminate all previously executed powers of attorney and rate and tariff service agreements, between it and any carrier utilizing its services, authorizing the publication and/or filing of intrastate collective rates within the State of Alabama;

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3. Cancel those provisions of its articles of incorporation, by-laws and procedures and every other rule, opinion, resolution, contract or statement of policy that has the purpose or effect of permitting, announcing, stating, explaining or agreeing to any business practice enjoined by the terms of this Order; and
4. Amend its by-laws to require members of ATA to observe the provisions of the Order as a condition of membership in ATA.

IV.

IT IS FURTHER ORDERED that, within fifteen (15) days after service upon it of this Order, Respondent shall mail or deliver a copy of this Order, under cover of the letter attached hereto as "Appendix," to each current member of Respondent engaged in the transportation of household goods, and for a period of three (3) years from the date of service of this Order, to each new member engaged in the transportation of household goods within ten (10) days of each such member's acceptance by Respondent.

V.

IT IS FURTHER ORDERED that Respondent notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, or any other proposed change in the corporation which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that Respondent shall file a written report within six (6) months of the date of service of this Order, and annually on the anniversary date of the original report for each of the five (5) years thereafter, and at such other times as the

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Commission may require by written notice to Respondent, setting forth in detail the manner and form in which it has complied with this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on December 4, 2023.

By the Commission, Commissioner Harbour not participating.

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APPENDIX

(Letterhead of the Alabama Trucking Association, Inc.)

Dear Member:

The Federal Trade Commission has ordered the Alabama Trucking Association, Inc. ("ATA") to cease and desist its tariff and collective rate-making activities. A copy of the Commission Decision and Order is enclosed.

In order that you may readily understand the terms of the Order, we have set forth its essential provisions, although you must realize that the Order itself is controlling, rather than the following explanation of its provisions:

(1) The ATA is prohibited from engaging in any collective rate-making activities, including the proposal, development or filing of tariffs which contain any collectively formulated rates for intrastate transportation services. Each member carrier must independently set its own rates for transportation of property or related services, goods or equipment between points within the State of Alabama, but may use ATA as a tariff publishing agent.

(2) ATA is prohibited from providing a forum for its members for the purpose of discussing rates.

(3) ATA is prohibited from urging, suggesting, encouraging or in any way attempting to influence the rates members charge for their intrastate transportation services; ATA may not provide non-public information to any carrier about rate changes ordered by another carrier.

(4) ATA is prohibited from maintaining any rate or tariff committee which discusses or formulates intrastate rates or rate proposals.

(5) ATA is given 120 days to cancel all tariffs and tariff

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supplements currently in effect and on file at the Alabama Public Service Commission which were prepared, developed or filed by ATA.

(6) ATA is required to amend its by-laws to require its members to observe the provisions of the Order as a condition of membership in ATA.

Sincerely yours,

[appropriate ATA officer]

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with Alabama Trucking Association, Inc. (“ATA” or “Respondent”) to resolve matters charged in an Administrative Complaint issued by the Commission on July 9, 2003. The agreement has been placed on the public record for thirty (30) days for receipt of comments from interested members of the public. The Agreement is for settlement purposes only and does not constitute an admission by ATA that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

The Commission’s decision to issue its Complaint in this matter was made after considering whether Respondent’s activities were protected by the state action defense. As discussed in detail in Section III below, a key element of the state action defense is the extent to which the State supervises private action. The facts developed during staff’s investigation pertaining to the extent to which Alabama supervised rates contained in tariffs filed by Respondent are discussed in this Analysis to illustrate how the Commission analyzed Respondent’s ability to establish a state action defense.¹

I. The Commission’s Complaint

The Complaint alleged that Respondent Alabama Trucking

¹ Settlement in this matter precludes the possibility of a litigated record. Thus, the Commission’s understanding of the facts as set forth in this Analysis is based on the record developed during staff’s investigation. The Commission has decided to include discussion of the relevant parts of the investigatory record to provide the best guidance it can on the scope of the state action defense and to facilitate comment on the proposed Consent Agreement.

Analysis

Association, Inc., a corporation, violated Section 5 of the Federal Trade Commission Act. Specifically, the Complaint alleged that Respondent agreed to engage, and had engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which was to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the household goods moving industry.

Respondent is an association organized for and serving its members, which are approximately 80 household goods movers that conduct business within the State of Alabama. One of the primary functions of ATA is preparing, and filing with the Alabama Public Service Commission, tariffs and supplements on behalf of its members. These tariffs and supplements contain rates and charges for the intrastate transportation of household goods and for related services.

The Complaint alleged that Respondent engaged in initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, which had the purpose or effect of fixing, establishing or stabilizing rates for the transportation of household goods in the State of Alabama.

The Complaint further alleged that Respondent organized and conducted meetings that provided a forum for discussion or agreement between competing carriers concerning or affecting rates and charges for the intrastate transportation of household goods.

The Complaint further alleged that Respondent's conduct was anticompetitive because it had the effect of raising, fixing, and stabilizing the prices of household goods moves. The acts of Respondent also had the effect of depriving consumers of the benefits of competition.

Analysis

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the conduct principally by means of a cease and desist order barring Respondent from continuing its practice of filing tariffs containing collective intrastate rates.

Paragraph II of the proposed Order bars Respondent from filing a tariff that contains collective intrastate rates. This provision will terminate Respondent's current practice of filing tariffs that contain intrastate rates that are the product of an agreement among movers in the State of Alabama. This paragraph also prohibits Respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. For example, the order bars Respondent from providing to other carriers certain non-public information.² It also bars Respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases.

Paragraph III of the proposed Order requires Respondent to cancel all tariffs that it has filed that contain intrastate collective rates. This provision will ensure that the collective intrastate rates now on file in the State of Alabama will no longer be in force, allowing for competitive rates in future individual mover tariffs. Paragraph III of the proposed Order also requires Respondent to cancel any provisions in its governing documents that permit it to engage in activities barred by the Order.

Paragraph IV of the proposed Order requires Respondent to send to its members a letter explaining the terms of the Order. This will make clear to members that they can no longer engage in collective rate-making activities.

² A state statute requires that carriers file their tariffs with the state and keep them open to public inspection. ALA. CODE § 37-3-20.

Analysis

Paragraphs V and VI of the proposed Order require Respondent to inform the Commission of any change in Respondent that could affect compliance with the Order and to file compliance reports with the Commission for a number of years. Paragraph VII of the proposed Order states that the Order will terminate in 20 years.

III. Opportunity for Modification of the Order

Respondent can seek to modify the proposed Order to permit it to engage in collective rate-making if it can demonstrate that the “state action” defense would apply to its conduct.³ The state action doctrine dates back to the Supreme Court’s 1943 opinion in *Parker v. Brown*, which held that, in light of the States’ status as sovereigns, and given basic principles of federalism, Congress would not have intended the Sherman Act to apply to the activities of States themselves.⁴ The defense also has been interpreted in limited circumstances to shield from antitrust scrutiny private firms’ activities that are conducted pursuant to state authority. States may not, however, simply authorize private parties to violate the antitrust laws.⁵ Instead, a State must substitute its own

³ 16 C.F.R. § 2.51. We discuss the state action defense below in some detail. *See also Indiana Household Movers and Warehousemen, Inc.*, File No. 021-0115 (Mar. 18, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf>; *Iowa Movers and Warehousemen’s Association*, File No. 021-0115 (Aug. 1, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/08/imwaanalysis.htm>; and *Minnesota Transport Services Association*, File No. 021-0115 (Aug. 1, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/08/mtsaanalysis.htm>.

⁴ 317 U.S. 341 (1943).

⁵ *Parker v. Brown*, 317 U.S. at 351 (“[A] state does not give immunity to those who violate the Sherman Act by authorizing

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control for that of the market.

Thus, the state action defense would be available to Respondent only if it could demonstrate that its conduct satisfied the strict two-pronged standard the Supreme Court set out in *California Retail Liquor Dealers Ass'n. v. Midcal Aluminum, Inc.*: “the challenged restraint must be ‘one clearly articulated and affirmatively expressed as state policy’” and “the policy must be ‘actively supervised’ by the state itself.”⁶

Under the first prong of *Midcal*'s two-part test, Respondent would be required to show that the State of Alabama had “clearly articulated and affirmatively expressed as state policy” the desire to replace competition with a regulatory scheme. With regard to this prong, it appears that under Alabama law tariffs must be “just and reasonable.”⁷ Respondent would meet its burden if it could show that this or some other provision of Alabama law constitutes a clear expression of state policy to displace competition and allow for collective rate-making among competitors.⁸

Under the second prong of the *Midcal* test, Respondent would

them to violate it, or declaring that their action is lawful.”).

⁶ 445 U.S. 97, 105 (1980) (“*Midcal*”) (quoting *City of Lafayette v. Louisiana Power & Light*, 435 U.S. 389, 410 (1978)). The “restraint” in this instance is the collective rate-setting. This articulation of the state action doctrine was reaffirmed by the Supreme Court in *FTC v. Ticor Title Insurance Co.* (“*Ticor*”), 504 U.S. 621, 633 (1992), where the Court noted that the gravity of the antitrust violation of price fixing requires exceptionally clear evidence of the State’s decision to supplant competition.

⁷ ALA. CODE § 37-3-19(b).

⁸ *United States v. Southern Motor Carriers Rate Conference*, 471 U.S. 48, 63-65 (1985).

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be required to demonstrate “active supervision” by state officials. The Supreme Court has made clear that the active supervision standard is a rigorous one. It is not enough that the State grants general authority for certain business conduct or that it approves private agreements with little review. As the Court held in *Midcal*, “The national policy in favor of competition cannot be thwarted by casting such a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement.”⁹ Rather, active supervision is designed to ensure that a private party’s anticompetitive action is shielded from antitrust liability only when “the State has effectively made [the challenged] conduct its own.”¹⁰

In order for state supervision to be adequate for state action purposes, state officials must engage in a “pointed re-examination” of the private conduct.¹¹ In this regard, the State must “have and exercise ultimate authority” over the challenged anticompetitive conduct.¹² To do so, state officials must exercise “sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.”¹³ One asserting the state action defense must demonstrate that the state agency has ascertained the relevant facts, examined the substantive merits of the private action, assessed whether that private action comports with the underlying statutory criteria established by the state legislature, and squarely ruled on the merits of the private action in a way sufficient to

⁹ *Midcal*, 445 U.S. at 105-06.

¹⁰ *Patrick v. Burget*, 486 U.S. 94, 106 (1988).

¹¹ *Midcal*, 445 U.S. at 106. *Accord*, *Ticor*, 504 U.S. at 634-35; *Patrick v. Burget*, 486 U.S. at 100-01.

¹² *Patrick v. Burget*, 486 U.S. at 101 (emphases added).

¹³ *Ticor*, 504 U.S. at 634-35.

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establish the challenged conduct as a product of deliberate state intervention rather than private choice.

IV. General Characteristics of Active Supervision

At its core, the active supervision requirement serves to identify those responsible for public policy decisions. The clear articulation requirement ensures that, if a State is to displace national competition norms, it must replace them with specific state regulatory standards; a State may not simply authorize private parties to disregard federal laws,¹⁴ but must genuinely substitute an alternative state policy. The active supervision requirement, in turn, ensures that responsibility for the ultimate conduct can properly be laid on the State itself, and not merely on the private actors. As the Court explained in *Ticor*:

States must accept political responsibility for actions they intend to undertake. . . . Federalism serves to assign political responsibility, not to obscure it. . . . For States which do choose to displace the free market with regulation, our insistence on real compliance with both parts of the *Midcal* test will serve to make clear that the State is responsible for the price fixing it has sanctioned and undertaken to control.¹⁵

Through the active supervision requirement, the Court furthers the fundamental principle of accountability that underlies federalism by ensuring that, if allowing anticompetitive conduct proves to be unpopular with a State's citizens, the state legislators will not be "insulated from the electoral ramifications of their decisions."¹⁶

¹⁴ *Parker*, 317 U.S. at 351.

¹⁵ 504 U.S. at 636.

¹⁶ See *New York v. United States*, 505 U.S. 144, 168-69 (1992).

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In short, clear articulation requires that a State enunciate an affirmative intent to displace competition and to replace it with a stated criterion. Active supervision requires the State to examine individual private conduct, pursuant to that regulatory regime, to ensure that it comports with that stated criterion. Only then can the underlying conduct accurately be deemed that of the State itself, and political responsibility for the conduct fairly be placed with the State.

Accordingly, under the Supreme Court's precedents, to provide meaningful active supervision, a State must (1) obtain sufficient information to determine the actual character of the private conduct at issue, (2) measure that conduct against the legislature's stated policy criteria, and (3) come to a clear decision that the private conduct satisfies those criteria, so as to make the final decision that of the State itself.

V. Standard for Active Supervision

There is no single procedural or substantive standard that the Supreme Court has held a State must adopt in order to meet the active supervision standard. Satisfying the Supreme Court's general standard for active supervision, described above, is and will remain the ultimate test for that element of the state action defense.

Nevertheless, in light of the foregoing principles, the Commission in this Analysis identifies the specific elements of an active supervision regime that it will consider in determining whether the active supervision prong of state action is met in future cases (as well as in any future action brought by Respondent to modify the terms of this proposed Order). They are three: (1) the development of an adequate factual record, including notice and opportunity to be heard; (2) a written decision on the merits; and (3) a specific assessment – both qualitative and quantitative – of how the private action comports with the substantive standards established by the state legislature. All three elements further the central purpose of the active supervision

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prong by ensuring that responsibility for the private conduct is fairly attributed to the State. Each will be discussed below.

**A. Development of an Adequate Factual Record,
Including Notice and Opportunity to Be Heard**

To meet the test for active state supervision, in this case Respondent would need to show that the State had in place an administrative body charged with the necessary review of filed tariffs and capable of developing an adequate factual record to do so.¹⁷ In *Ticor*, the Court quoted language from earlier lower court cases setting out a list of organizational and procedural characteristics relevant as the “beginning point” of an effective state program:

[T]he state’s program is in place, is staffed and funded, grants to the state officials ample power and the duty to regulate pursuant to declared standards of state policy, is enforceable in the state’s courts, and demonstrates some basic level of activity directed towards seeing that the private actors carry out the state’s policy and not simply their own policy¹⁸

¹⁷ At the time of any request for a modification, Respondent will be required to produce evidence of what the state reviewing agency is likely to do in response to collective rate-making. We recognize that this involves some prediction and uncertainty, particularly when the Respondent requests an order modification on the basis of a state review program that might be authorized but not yet operating, as the Respondent will still be under order. In such cases it may be appropriate for the Respondent to show what the state program is designed, directed, or organized to do. If a particular state agency is already conducting reviews in some related area, evidence of its approach to these tasks will be particularly relevant.

¹⁸ *Ticor*, 504 U.S. at 637 (citations omitted).

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Moreover, that body would need to be capable of compiling, and actually compile, an adequate factual record to assess the nature and impact of the private conduct in question. The precise factual record that would be required would depend on the substantive norm that the State has provided; the critical question is whether the record has sufficient facts for the reviewing body sensibly to determine that the State's substantive regulatory requirements have been achieved. In the typical case in which the State has articulated a criterion of consumer impact, obtaining reliable, timely, and complete economic data would be central to the regulatory board's ability to determine if the State's chosen criterion has been satisfied.¹⁹ Timeliness in particular is an ongoing concern; if the private conduct is to remain in place for an extended period of time, then periodic state reviews of that private conduct using current economic data are important to ensure that the restraint remains that of the State, and not of the private actors.

In Alabama, the State had in place rules and regulations pertaining to, and had staff assigned to review, household goods tariffs. Respondent sent to the State fairly specific written assertions that movers' costs had increased. In addition, the State monitored fuel costs and labor rates as well as the rates contained in the federal household goods tariff.

Nevertheless, Respondent made no showing that the State had done the necessary research into the economic conditions of the moving industry in Alabama that would enable it to assess the impact of the Respondent's proposal.²⁰ Moreover, Respondent

¹⁹ As the *Ticor* Court held, "state officials [must] have undertaken the necessary steps to determine the specifics of the price-fixing or ratesetting scheme." *Id.* at 638.

²⁰ *Cf. New England Motor Rate Bureau, Inc.*, 112 F.T.C. 200, 233, 266, 279-80 (1989) (active supervision not found because, *inter alia*, the State had "never conducted an economic study of

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did not produce evidence that the State sought independently to verify the accuracy of the financial information submitted by the movers.²¹

Additionally, in assembling an adequate factual record, the procedural value of notice and opportunity to comment is well established. These procedural elements, which have evolved in various contexts through common law, through state and federal constitutional law, and through Administrative Procedure Act rulemakings,²² are powerful engines for ensuring that relevant facts – especially those facts that might tend to contradict the proponent’s contentions – are brought to the state decision-maker’s attention. In Alabama, it has been many years since the State has held a hearing to consider the rates contained in the

the intrastate trucking industry nor of the effects of its regulatory policy on the intrastate trucking industry within the state”). Although the First Circuit reversed the Commission’s decision, *New England Motor Rate Bureau v. FTC*, 908 F.2d 1064 (1st Cir. 1990), the First Circuit’s standard for active supervision was later found to be “insufficient” in *Ticor*. 504 U.S. at 637.

²¹ *Cf. United States v. Southern Motor Carriers Rate Conference*, 467 F. Supp. 471, 477 (N.D.Ga. 1979), *aff’d*, 702 F.2d 543 (5th Cir. Unit B 1983) (active supervision found where, among other things, the State undertook “on-site review and verification of motor carrier books and records”), *rev’d on other grounds*, 471 U.S. 48 (1985).

²² The Administrative Procedure Act defines a rule, in part, as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” 5 U.S.C. § 551(4). Actions “concerned with the approval of ‘tariffs’ or rate schedules filed by public utilities and common carriers” are typical examples of rulemaking proceedings. E. Gellhorn & R. Levin, *Administrative Law & Process* 300 (1997).

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tariff. In addition, many rate increases have been approved without a hearing to consider movers' requests for rate increases and without the opportunity for public comment on proposed rate increases.

B. A Written Decision

A second important element the Commission will look to in determining whether there has been active supervision is whether the state board renders its decision in writing. Though not essential, the existence of a written decision is normally the clearest indication that the board (1) genuinely has assessed whether the private conduct satisfies the legislature's stated standards and (2) has directly taken responsibility for that determination. Through a written decision, whether rejecting or (the more critical context) approving particular private conduct that would otherwise violate the federal antitrust laws, the state board would provide analysis and reasoning, and supporting evidence, that the private conduct furthers the legislature's objectives.²³ In Alabama, the State does not issue written decisions on household goods rates. Many rate increases have been granted without a written explanation of the evidence supporting the increases and without a record of the State's analysis or reasoning in granting the increases.

²³ A record preserved by other means, such as audio or video recording technology, might also suffice, provided that it demonstrated that the board had (1) genuinely assessed the private conduct and (2) taken direct responsibility. Such an audio or video recording, however, will be an adequate substitute for a written opinion only when it provides a sufficiently transparent and decipherable view of the decision-making proceeding to facilitate meaningful public review and comment.

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C. Qualitative and Quantitative Compliance with State Policy Objectives

In determining active supervision, the substance of the State's decision is critical. Its fundamental purpose must be to determine that the private conduct meets the state legislature's stated criteria. Federal antitrust law does not seek to impose federal substantive standards on state decision-making, but it does require that the States – in displacing federal law – meet their own stated standards. As the *Ticor* Court explained:

Our decisions make clear that the purpose of the active supervision inquiry is not to determine whether the State has met some normative standard, such as efficiency, in its regulatory practices. Its purpose is to determine whether the State has exercised sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties. Much as in causation inquiries, the analysis asks whether the State has played a substantial role in determining the specifics of the economic policy. The question is not how well state regulation works but whether the anticompetitive scheme is the State's own.²⁴

Thus, a decision by a state board that assesses both qualitatively and quantitatively whether the “details of the rates or prices” satisfy the state criteria ensures that it is the State, and not the private parties, that determines the substantive policy. There should be evidence of the steps the State took in analyzing the rates filed and the criteria it used in evaluating those rates. There should also be evidence showing whether the State independently verified the accuracy of financial data submitted and whether it relied on accurate and representative samples of data. There should be evidence that the State has a thorough understanding of

²⁴ *Ticor*, 504 U.S. at 634-35.

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the consequences of the private parties' proposed action. Tariffs, for instance, can be complex, and there should be evidence that the State not only has analyzed the actual rates charged but also has analyzed the complex rules that may directly or indirectly impact the rates contained in the tariff.

If the State has chosen to include in its statute a requirement that the regulatory body evaluate the impact of particular conduct on "competition," "consumer welfare," or some similar criterion, then – to meet the standard for active supervision – there should be evidence that the State has closely and carefully examined the likely impact of the conduct on consumers. Because the central purpose of the federal antitrust laws is also to protect competition and consumer welfare,²⁵ conduct that would run counter to those federal laws should not be lightly assumed to be consistent with parallel state goals. Especially when, as here, the underlying private conduct alleged is price fixing – which, as the *Ticor* Court noted, is possibly the most "pernicious" antitrust offense²⁶ – a careful consideration of the specific monetary impact on consumers is critical to any assessment of an overall impact on consumer welfare. That consideration should include an express quantitative assessment, based on reliable economic data, of the specific likely impact upon consumers.

It bears emphasizing that States need not choose to enact criteria such as promoting "competition" or "consumer welfare" – the central end of federal antitrust law. A State could instead enact some other criterion. Then, the State's decision would need to assess whether that objective had been met.

²⁵ Indeed, consideration of consumer impact is at the heart of "[a] national policy" that preserves "the free market and . . . a system of free enterprise without price fixing or cartels." *Id.* at 632.

²⁶ *Id.* at 639 ("No antitrust offense is more pernicious than price fixing.").

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On the other hand, if a State does not disavow (either expressly or through the promulgation of wholly contrary regulatory criteria) that consumer welfare is state regulatory policy, it should address consumer welfare in its regulatory analysis. In claiming the state action defense, a respondent should demonstrate that the state board, in evaluating arguably anticompetitive conduct, had carefully considered and quantified the likely impact of that conduct on consumers as a central element of deciding whether to approve that conduct.²⁷

In the present case, Alabama has expressly chosen to give significant consideration to, among other state interests, the interests of consumers when determining whether rates are “just and reasonable”:

In the exercise of its power to prescribe just and reasonable rates for the transportation of passengers or property by common carriers . . . the commission shall give due consideration, among other things, to

* * * *

the need, in public interest, of adequate and efficient transportation service by such carriers at the lowest cost consistent with the furnishing of such service.²⁸

Thus, to establish active supervision, Respondent would be obligated to show that the State, when approving the rates at issue, performed an analysis and quantification of whether the rates to consumers were “at the lowest cost consistent with the furnishing of service.” Here, there was some indication that a staff member

²⁷ This requirement is based on the principle that the national policy favoring competition “is an essential part of the economic and legal system within which the separate States administer their own laws.” *Id.* at 632.

²⁸ ALA. CODE § 37-3-19(g).

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reviewed movers' financial data to determine whether movers' operating ratios were within a specified range of operating ratios.²⁹ Nevertheless, Respondent did not provide evidence that the State had done any analysis and quantification of whether the rates satisfied the statutory objective.

VI. Opportunity for Public Comment

The standards of active supervision remain those laid out by the Supreme Court in *Midcal* and its progeny. Those standards have been explained in detail above to further illustrate how they would apply should Respondent seek to modify this proposed Order. Applying these standards, the Commission believes, will further the principles of federalism and accountability enunciated by the Supreme Court, will help clarify for States and private parties the reach of federal antitrust law, and will ultimately redound to the benefit of consumers.

These review techniques may also help to show active state supervision in other contexts. In this Analysis we have described particular techniques that can show active supervision in the context of tariff filings. Such filings often involve recurring, concrete acts of private rate setting that tend to automatically trigger review on the occasion of each such filing. As noted above, however, if a rate filing remains in place for a prolonged period of time, the state will have an obligation to review the level of those rates on an ongoing basis. Similarly, there may be other industries where specific events do not trigger a review of private conduct, yet where the state has still displaced competition and therefore the state action defense would apply only where it could

²⁹ Cf. *United States v. Southern Motor Carriers Rate Conference*, 467 F. Supp. 471, 477 (N.D. Ga. 1979), *aff'd*, 702 F.2d 543 (5th Cir. Unit B 1983) (active supervision established where, among other things, the State reviewed a request for an increase in motor carrier rates by analyzing motor carriers' operating ratios), *rev'd on other grounds*, 471 U.S. 48 (1985).

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be shown that the conduct was being actively supervised. We believe that the review principles described here can be adapted to those circumstances as well. Evidence of active supervision then might be required, not in connection with particular events, but rather on a reasonable periodic basis. That supervision might still involve the elements discussed here, such as notice, analysis in light of the statutory purposes, and a written decision.

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or to modify their terms in any way.

Complaint

IN THE MATTER OF

MOVERS CONFERENCE OF MISSISSIPPI, INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket 9308; File No. 0210115**Complaint, July 8, 2003--Decision, December 4, 2003*

This consent order, among other things, prohibits Respondent Movers Conference of Mississippi, Inc. – an association with, as members, approximately 39 household goods movers that conduct business within the State of Mississippi – from filing tariffs that contain collective intrastate rates. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. In addition, the order prohibits the respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases. The order also requires the respondent to cancel all tariffs it has filed that contain intrastate collective rates; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send its members a letter explaining the terms of the order.

Participants

For the Commission: *Dana Abrahamsen, Patrick J. Roach, Richard B. Dagen, John Howell and Mary T. Coleman.*

For the Respondent: *Keith Allison, pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Movers Conference of Mississippi, Inc. (hereinafter sometimes referred to as “respondent” or “MCM”), a corporation, has violated and is now violating the provisions of Section 5 of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

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NATURE OF THE CASE

This matter concerns horizontal agreements among competing household goods movers that, through respondent, file tariffs for intrastate moving services in Mississippi. The tariffs contain collective rates that participating movers charge consumers for moving services. Through these tariffs, the participating movers engage in a horizontal agreement to fix prices for their services.

RESPONDENT AND ITS MEMBERS

PARAGRAPH 1. Respondent Movers Conference of Mississippi, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Mississippi, with its office and principal place of business located at P.O. Box 961, Jackson, Mississippi.

PARAGRAPH 2. Respondent is an association organized for and serving its members' interests, including their economic interests, by promoting, fostering, and advancing the household goods moving industry in the State of Mississippi. One of the primary functions of respondent is the initiation, preparation, development, dissemination, and filing with the Mississippi Public Service Commission of tariffs and supplements thereto on behalf of and as agent for its members. Said tariffs and supplements contain rates and charges for the intrastate and local transportation of household goods and for related services, including, among other things, transporting bulky articles; packing cartons and crates; and extra charges for elevator, stair, and long distance carrying of items. (For purposes of this complaint, the term "tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Mississippi, including updates, revisions, and/or amendments, including general rules and regulations.)

PARAGRAPH 3. Pursuant to Mississippi state law, each household goods mover is required to file a tariff with the Mississippi Public Service Commission containing the carrier's

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rates, fares, or charges for the intrastate transportation of household goods. By Mississippi law, a household goods mover is not permitted to charge a rate, fare, or charge different from those contained in its tariff or supplements thereto once the Mississippi Public Service Commission has accepted it.

PARAGRAPH 4. Members of respondent are engaged, among other things, in the business of providing transportation and other services for compensation as household goods movers between points within the State of Mississippi. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other household goods movers.

PARAGRAPH 5. The membership of MCM consists of approximately 39 household goods movers that conduct business within the State of Mississippi. MCM members receive compensation for intrastate moves. MCM's Rate and Tariff Committee conducts MCM's tariff-related activities. The Rate and Tariff Committee's Board of Directors is comprised of one representative for each MCM member; these representatives designate officers.

JURISDICTION

PARAGRAPH 6. The acts and practices of respondent set forth in Paragraph 7 have been and are now in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, and respondent is subject to the jurisdiction of the Federal Trade Commission. Among other things, the aforesaid acts and practices:

- (A) Affect the flow of substantial sums of money from the federal government, business, and other private parties to the respondent's members for rendering transportation services, which money flows across state lines;

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(B) Affect the purchase and use of equipment and other goods and services by respondent's members that are shipped in interstate commerce;

(C) Include the use of the United States mail and other instruments of interstate commerce in furthering the agreements described below; and

(D) Are supported by the receipt of dues and fees for publications and services from out-of-state members and others.

THE CHALLENGED CONDUCT

PARAGRAPH 7. For many years and continuing up to and including the date of the filing of this complaint, respondent, its members, its officers and directors, and others have agreed to engage, and have engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which is, was, or may be to unlawfully hinder, restrain, restrict, suppress, or eliminate competition among household goods movers in the intrastate Mississippi household goods moving industry.

Pursuant to, and in furtherance of, said agreement and concert of action, respondent, its members and others have engaged and continue to engage in the following acts, policies, and practices, among others:

(A) Initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, with the purpose or effect of fixing, establishing, stabilizing or otherwise tampering with rates and charges for the transportation of household goods between points within the State of Mississippi;

(B) Participating in and continuing to participate in the collectively set rates;

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(C) Filing collectively set rates with the Mississippi Public Service Commission; and

(D) Initiating, organizing, coordinating, and conducting meetings or providing a forum for any discussion or agreement among competing carriers concerning or affecting rates charged or proposed to be charged for the intrastate transportation of household goods; or otherwise influencing its members to raise their rates, charge the same or uniform rates, or participate or continue to participate in the collectively set rates.

PARAGRAPH 8. The acts and practices of respondent, its members and others, as alleged in Paragraph 7, have had and are now having the effects, among others, of:

(A) Raising, fixing, stabilizing, pegging, maintaining, or otherwise interfering or tampering with the prices of household goods moves;

(B) Restricting, restraining, hindering, preventing, or frustrating price competition in the household goods moving industry; and

(C) Depriving consumers of the benefits of competition.

THE VIOLATION CHARGED

PARAGRAPH 9. The acts, policies and practices of respondent, its members and others, as herein alleged, were and are to the prejudice and injury of the public and constituted and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

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Notice

Notice is hereby given to the Respondent that the eighth day of October, 2003, at 10:00 a.m., or such later date as determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the FTC Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded to you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under § 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings and the right to appeal the initial decision to the Commission under § 3.52 of said Rules.

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Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions, and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a Respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice of Contemplated Relief

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that respondent's conduct violated Section 5 of the Federal Trade Commission Act as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including but not limited to:

1. Requiring respondent to cease and desist from preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment.
2. Requiring respondent to cease and desist from providing information to any carrier about rate changes considered or

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made by any other carrier employing the publishing services of respondent prior to the time at which such rate changes become a matter of public record.

3. Requiring respondent to cease and desist from inviting, coordinating or providing a forum (including maintaining any rate or tariff committee) for any discussion or agreement between or among competing carriers concerning rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment.
4. Requiring respondent to cease and desist from suggesting, urging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided.
5. Requiring respondent to cease and desist from preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.
6. Requiring respondent to cancel all tariffs and any supplements thereto on file with the state that establish rates for transportation of property or related services, goods or equipment.
7. Requiring respondent to cancel those provisions of its articles of incorporation, by-laws and procedures, tariff service agreements and every other rule that has the purpose or effect of permitting, announcing, explaining or agreeing to any business practice enjoined by the terms of any order, and to amend its by-laws to require members to observe the provisions of any order.

Complaint

8. Requiring respondent to make public, in a manner likely to reach as many members as possible, the nature of the relief ordered by the Commission.
9. Such additional relief as is necessary to correct or remedy the violations alleged in the complaint.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighth day of July, 2003, issues its complaint against MCM.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having heretofore issued its Complaint charging the Movers Conference of Mississippi, Inc. (“MCM”), hereinafter sometimes referred to as “Respondent,” with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Respondent having been served with a copy of that Complaint, together with a Notice of Contemplated Relief; and

Respondent and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with Commission Rule 3.25(c), 16 C.F.R. § 3.25(c); and

The Commission having thereafter considered the matter and thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 3.25(f), 16 C.F.R. § 3.25(f), the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Movers Conference of Mississippi, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Mississippi, with its office and

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principal place of business located at P.O. Box 961, Jackson, Mississippi.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "MCM" means the Movers Conference of Mississippi, Inc., its officers, executive board, committees, parents, representatives, agents, employees, successors and assigns;
- B. "Carrier" means a common carrier of property by motor vehicle;
- C. "Intrastate transportation" means the pickup or receipt, transportation and delivery of property hauled between points within the State of Mississippi for compensation by a carrier authorized by the Mississippi Public Service Commission to engage therein;
- D. "Member" means any carrier or other person that pays dues or belongs to MCM or to any successor corporation;
- E. "Tariff" means the publication stating the rates of a carrier for the transportation of property between points within the State of Mississippi, including updates, revisions, and/or amendments, including general rules and regulations;

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- F. "Rate" means a charge, payment or price fixed according to a ratio, scale or standard for direct or indirect transportation service;
- G. "Collective rates" means any rate or charge established under any contract, agreement, understanding, plan, program, combination or conspiracy between two or more competing carriers, or between any two or more carriers and Respondent; and
- H. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

II.

IT IS FURTHER ORDERED that Respondent, its successors and assigns, and its officers, agents, representatives, directors and employees, directly or through any corporation, subsidiary, division or other device, shall forthwith cease and desist from entering into and within 120 days after service upon it of this Order cease and desist from adhering to or maintaining, directly or indirectly, any contract, agreement, understanding, plan, program, combination or conspiracy to fix, stabilize, raise, maintain or otherwise interfere or tamper with the rates charged by two or more carriers for the intrastate transportation of property or related services, goods or equipment, including, but not limited to:

1. Knowingly preparing, developing, disseminating or filing a proposed or existing tariff that contains collective rates for the intrastate transportation of property or other related services, goods or equipment;
2. Providing information to any carrier about rate changes considered or made by any other carrier employing the publishing services of Respondent prior to the time at which such rate change becomes a matter of public record;

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3. Inviting, coordinating or providing a forum (including publication of an informational bulletin) for any discussion or agreement between or among competing carriers concerning rates charged or proposed to be charged by carriers for the intrastate transportation of property or related services, goods or equipment;
4. Suggesting, urging, encouraging, persuading or in any way influencing members to charge, file or adhere to any existing or proposed tariff provision which affects rates, or otherwise to charge or refrain from charging any particular price for any services rendered or goods or equipment provided;
5. Maintaining any rate or tariff committee or other entity to consider, pass upon or discuss intrastate rates or rate proposals; and
6. Preparing, developing, disseminating or filing a proposed or existing tariff containing automatic changes to rates charged by two or more carriers.

III.

IT IS FURTHER ORDERED that Respondent shall, within 120 days after service upon it of this Order:

1. Cancel all tariffs and any supplements thereto on file with the Mississippi Public Service Commission that establish rates for transportation of property or related services, goods or equipment by common carriers in the State of Mississippi and take such action as may be necessary to effectuate cancellation and withdrawal;
2. Terminate all previously executed powers of attorney and rate and tariff service agreements, between it and any carrier utilizing its services, authorizing the publication and/or filing of intrastate collective rates within the State of Mississippi;

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3. Cancel those provisions of its articles of incorporation, by-laws and procedures and every other rule, opinion, resolution, contract or statement of policy that has the purpose or effect of permitting, announcing, stating, explaining or agreeing to any business practice enjoined by the terms of this Order; and
4. Amend its by-laws to require members of MCM to observe the provisions of the Order as a condition of membership in MCM.

IV.

IT IS FURTHER ORDERED that, within fifteen (15) days after service upon it of this Order, Respondent shall mail or deliver a copy of this Order, under cover of the letter attached hereto as "Appendix," to each current member of Respondent engaged in the transportation of household goods, and for a period of three (3) years from the date of service of this Order, to each new member engaged in the transportation of household goods within ten (10) days of each such member's acceptance by Respondent.

V.

IT IS FURTHER ORDERED that Respondent notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, or any other proposed change in the corporation which may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that Respondent shall file a written report within six (6) months of the date of service of this Order, and annually on the anniversary date of the original report for each of the five (5) years thereafter, and at such other times as the Commission may require by written notice to Respondent, setting

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forth in detail the manner and form in which it has complied with this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on December 4, 2023.

By the Commission, Commissioner Harbour not participating.

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APPENDIX

(Letterhead of the Movers Conference of Mississippi, Inc.)

Dear Member:

The Federal Trade Commission has ordered the Movers Conference of Mississippi, Inc. ("MCM") to cease and desist its tariff and collective rate-making activities. A copy of the Commission Decision and Order is enclosed.

In order that you may readily understand the terms of the Order, we have set forth its essential provisions, although you must realize that the Order itself is controlling, rather than the following explanation of its provisions:

- (1) The MCM is prohibited from engaging in any collective rate-making activities, including the proposal, development or filing of tariffs which contain any collectively formulated rates for intrastate transportation services. Each member carrier must independently set its own rates for transportation of property or related services, goods or equipment between points within the State of Mississippi, but may use MCM as a tariff publishing agent.
- (2) MCM is prohibited from providing a forum for its members for the purpose of discussing rates.
- (3) MCM is prohibited from urging, suggesting, encouraging or in any way attempting to influence the rates members charge for their intrastate transportation services; MCM may not provide non-public information to any carrier about rate changes ordered by another carrier.
- (4) MCM is prohibited from maintaining any rate or tariff committee which discusses or formulates intrastate rates or rate proposals.

Decision and Order

(5) MCM is given 120 days to cancel all tariffs and tariff supplements currently in effect and on file at the Mississippi Public Service Commission which were prepared, developed or filed by MCM.

(6) MCM is required to amend its by-laws to require its members to observe the provisions of the Order as a condition of membership in MCM.

Sincerely yours,

[appropriate MCM officer]

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with Movers Conference of Mississippi, Inc. (“MCM” or “Respondent”) to resolve matters charged in an Administrative Complaint issued by the Commission on July 9, 2003. The agreement has been placed on the public record for thirty (30) days for receipt of comments from interested members of the public. The Agreement is for settlement purposes only and does not constitute an admission by MCM that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

The Commission’s decision to issue its Complaint in this matter was made after considering whether Respondent’s activities were protected by the state action defense. As discussed in detail in Section III below, a key element of the state action defense is the extent to which the State supervises private action. The facts developed during staff’s investigation pertaining to the extent to which Mississippi supervised rates contained in tariffs filed by Respondent are discussed in this Analysis to illustrate how the Commission analyzed Respondent’s ability to establish a state action defense.¹

¹ Settlement in this matter precludes the possibility of a litigated record. Thus, the Commission’s understanding of the facts as set forth in this Analysis is based on the record developed during staff’s investigation. The Commission has decided to include discussion of the relevant parts of the investigatory record to provide the best guidance it can on the scope of the state action defense and to facilitate comment on the proposed Consent Agreement.

Analysis

I. The Commission's Complaint

The Complaint alleged that Respondent Movers Conference of Mississippi, Inc., a corporation, violated Section 5 of the Federal Trade Commission Act. Specifically, the Complaint alleged that Respondent agreed to engage, and had engaged, in a combination and conspiracy, an agreement, concerted action or unfair and unlawful acts, policies and practices, the purpose or effect of which was to unlawfully hinder, restrain, restrict, suppress or eliminate competition among household goods movers in the household goods moving industry.

Respondent is an association organized for and serving its members, which are approximately 39 household goods movers that conduct business within the State of Mississippi. One of the primary functions of MCM is preparing, and filing with the Mississippi Public Service Commission, tariffs and supplements on behalf of its members. These tariffs and supplements contain rates and charges for the intrastate transportation of household goods and for related services.

The Complaint alleged that Respondent engaged in initiating, preparing, developing, disseminating, and taking other actions to establish and maintain collective rates, which had the purpose or effect of fixing, establishing or stabilizing rates for the transportation of household goods in the State of Mississippi.

The Complaint further alleged that Respondent organized and conducted meetings that provided a forum for discussion or agreement between competing carriers concerning or affecting rates and charges for the intrastate transportation of household goods.

The Complaint further alleged that Respondent's conduct was anticompetitive because it had the effect of raising, fixing, and stabilizing the prices of household goods moves. The acts of Respondent also had the effect of depriving consumers of the benefits of competition.

Analysis

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the conduct principally by means of a cease and desist order barring Respondent from continuing its practice of filing tariffs containing collective intrastate rates.

Paragraph II of the proposed Order bars Respondent from filing a tariff that contains collective intrastate rates. This provision will terminate Respondent's current practice of filing tariffs that contain intrastate rates that are the product of an agreement among movers in the State of Mississippi. This paragraph also prohibits Respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. For example, the order bars Respondent from providing to other carriers certain non-public information.² It also bars Respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases.

Paragraph III of the proposed Order requires Respondent to cancel all tariffs that it has filed that contain intrastate collective rates. This provision will ensure that the collective intrastate rates now on file in the State of Mississippi will no longer be in force, allowing for competitive rates in future individual mover tariffs. Paragraph III of the proposed Order also requires Respondent to cancel any provisions in its governing documents that permit it to engage in activities barred by the Order.

Paragraph IV of the proposed Order requires Respondent to send to its members a letter explaining the terms of the Order. This will make clear to members that they can no longer engage in collective rate-making activities.

² A state statute requires that carriers file their tariffs and make them available to the public. MISS. CODE ANN. § 77-7-211.

Analysis

Paragraphs V and VI of the proposed Order require Respondent to inform the Commission of any change in Respondent that could affect compliance with the Order and to file compliance reports with the Commission for a number of years. Paragraph VII of the proposed Order states that the Order will terminate in 20 years.

III. Opportunity for Modification of the Order

Respondent can seek to modify the proposed Order to permit it to engage in collective rate-making if it can demonstrate that the “state action” defense would apply to its conduct.³ The state action doctrine dates back to the Supreme Court’s 1943 opinion in *Parker v. Brown*, which held that, in light of the States’ status as sovereigns, and given basic principles of federalism, Congress would not have intended the Sherman Act to apply to the activities of States themselves.⁴ The defense also has been interpreted in limited circumstances to shield from antitrust scrutiny private firms’ activities that are conducted pursuant to state authority. States may not, however, simply authorize private parties to violate the antitrust laws.⁵ Instead, a State must substitute its own

³ 16 C.F.R. § 2.51. We discuss the state action defense below in some detail. *See also Indiana Household Movers and Warehousemen, Inc.*, File No. 021-0115 (Mar. 18, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf>; *Iowa Movers and Warehousemen’s Association*, File No. 021-0115 (Aug. 1, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/08/imwaanalysis.htm>; and *Minnesota Transport Services Association*, File No. 021-0115 (Aug. 1, 2003) (proposed consent order) available at <http://www.ftc.gov/os/2003/08/mtsaanalysis.htm>.

⁴ 317 U.S. 341 (1943).

⁵ *Parker v. Brown*, 317 U.S. at 351 (“[A] state does not give immunity to those who violate the Sherman Act by authorizing

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control for that of the market.

Thus, the state action defense would be available to Respondent only if it could demonstrate that its conduct satisfied the strict two-pronged standard the Supreme Court set out in *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*: “the challenged restraint must be ‘one clearly articulated and affirmatively expressed as state policy’” and “the policy must be ‘actively supervised’ by the state itself.”⁶

Under the first prong of *Midcal*'s two-part test, Respondent would be required to show that the State of Mississippi had “clearly articulated and affirmatively expressed as state policy” the desire to replace competition with a regulatory scheme. With regard to this prong, it appears that under Mississippi law tariffs must be “just and reasonable.”⁷ Respondent would meet its burden if it could show that these or some other provision of Mississippi law constitutes a clear expression of state policy to displace competition and allow for collective rate-making among competitors.⁸

them to violate it, or declaring that their action is lawful.”).

⁶ 445 U.S. 97, 105 (1980) (“*Midcal*”) (quoting *City of Lafayette v. Louisiana Power & Light*, 435 U.S. 389, 410 (1978)). The “restraint” in this instance is the collective rate-setting. This articulation of the state action doctrine was reaffirmed by the Supreme Court in *FTC v. Ticor Title Insurance Co.* (“*Ticor*”), 504 U.S. 621, 633 (1992), where the Court noted that the gravity of the antitrust violation of price fixing requires exceptionally clear evidence of the State’s decision to supplant competition.

⁷ MISS. CODE ANN. § 77-7-151; MISS. CODE ANN. § 77-7-221.

⁸ *United States v. Southern Motor Carriers Rate Conference*, 471 U.S. 48, 63-65 (1985).

Analysis

Under the second prong of the *Midcal* test, Respondent would be required to demonstrate “active supervision” by state officials. The Supreme Court has made clear that the active supervision standard is a rigorous one. It is not enough that the State grants general authority for certain business conduct or that it approves private agreements with little review. As the Court held in *Midcal*, “The national policy in favor of competition cannot be thwarted by casting such a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement.”⁹ Rather, active supervision is designed to ensure that a private party’s anticompetitive action is shielded from antitrust liability only when “the State has effectively made [the challenged] conduct its own.”¹⁰

In order for state supervision to be adequate for state action purposes, state officials must engage in a “pointed re-examination” of the private conduct.¹¹ In this regard, the State must “have and exercise ultimate authority” over the challenged anticompetitive conduct.¹² To do so, state officials must exercise “sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.”¹³ One asserting the state action defense must demonstrate that the state agency has ascertained the relevant facts, examined the substantive merits of the private action, assessed whether that private action comports with the underlying

⁹ *Midcal*, 445 U.S. at 105-06.

¹⁰ *Patrick v. Burget*, 486 U.S. 94, 106 (1988).

¹¹ *Midcal*, 445 U.S. at 106. *Accord*, *Ticor*, 504 U.S. at 634-35; *Patrick v. Burget*, 486 U.S. at 100-01.

¹² *Patrick v. Burget*, 486 U.S. at 101 (emphases added).

¹³ *Ticor*, 504 U.S. at 634-35.

Analysis

statutory criteria established by the state legislature, and squarely ruled on the merits of the private action in a way sufficient to establish the challenged conduct as a product of deliberate state intervention rather than private choice.

IV. General Characteristics of Active Supervision

At its core, the active supervision requirement serves to identify those responsible for public policy decisions. The clear articulation requirement ensures that, if a State is to displace national competition norms, it must replace them with specific state regulatory standards; a State may not simply authorize private parties to disregard federal laws,¹⁴ but must genuinely substitute an alternative state policy. The active supervision requirement, in turn, ensures that responsibility for the ultimate conduct can properly be laid on the State itself, and not merely on the private actors. As the Court explained in *Ticor*:

States must accept political responsibility for actions they intend to undertake. . . . Federalism serves to assign political responsibility, not to obscure it. . . . For States which do choose to displace the free market with regulation, our insistence on real compliance with both parts of the *Midcal* test will serve to make clear that the State is responsible for the price fixing it has sanctioned and undertaken to control.¹⁵

Through the active supervision requirement, the Court furthers the fundamental principle of accountability that underlies federalism by ensuring that, if allowing anticompetitive conduct proves to be unpopular with a State's citizens, the state legislators will not be

¹⁴ *Parker*, 317 U.S. at 351.

¹⁵ 504 U.S. at 636.

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“insulated from the electoral ramifications of their decisions.”¹⁶

In short, clear articulation requires that a State enunciate an affirmative intent to displace competition and to replace it with a stated criterion. Active supervision requires the State to examine individual private conduct, pursuant to that regulatory regime, to ensure that it comports with that stated criterion. Only then can the underlying conduct accurately be deemed that of the State itself, and political responsibility for the conduct fairly be placed with the State.

Accordingly, under the Supreme Court’s precedents, to provide meaningful active supervision, a State must (1) obtain sufficient information to determine the actual character of the private conduct at issue, (2) measure that conduct against the legislature’s stated policy criteria, and (3) come to a clear decision that the private conduct satisfies those criteria, so as to make the final decision that of the State itself.

V. Standard for Active Supervision

There is no single procedural or substantive standard that the Supreme Court has held a State must adopt in order to meet the active supervision standard. Satisfying the Supreme Court’s general standard for active supervision, described above, is and will remain the ultimate test for that element of the state action defense.

Nevertheless, in light of the foregoing principles, the Commission in this Analysis identifies the specific elements of an active supervision regime that it will consider in determining whether the active supervision prong of state action is met in future cases (as well as in any future action brought by Respondent to modify the terms of this proposed Order). They are

¹⁶ See *New York v. United States*, 505 U.S. 144, 168-69 (1992).

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three: (1) the development of an adequate factual record, including notice and opportunity to be heard; (2) a written decision on the merits; and (3) a specific assessment – both qualitative and quantitative – of how the private action comports with the substantive standards established by the state legislature. All three elements further the central purpose of the active supervision prong by ensuring that responsibility for the private conduct is fairly attributed to the State. Each will be discussed below.

**A. Development of an Adequate Factual Record,
Including Notice and Opportunity to Be Heard**

To meet the test for active state supervision, in this case Respondent would need to show that the State had in place an administrative body charged with the necessary review of filed tariffs and capable of developing an adequate factual record to do so.¹⁷ In *Ticor*, the Court quoted language from earlier lower court cases setting out a list of organizational and procedural characteristics relevant as the “beginning point” of an effective state program:

[T]he state’s program is in place, is staffed and funded, grants to the state officials ample power and the duty to regulate pursuant to declared standards of state policy, is

¹⁷ At the time of any request for a modification, Respondent will be required to produce evidence of what the state reviewing agency is likely to do in response to collective rate-making. We recognize that this involves some prediction and uncertainty, particularly when the Respondent requests an order modification on the basis of a state review program that might be authorized but not yet operating, as the Respondent will still be under order. In such cases it may be appropriate for the Respondent to show what the state program is designed, directed, or organized to do. If a particular state agency is already conducting reviews in some related area, evidence of its approach to these tasks will be particularly relevant.

Analysis

enforceable in the state's courts, and demonstrates some basic level of activity directed towards seeing that the private actors carry out the state's policy and not simply their own policy¹⁸

Moreover, that body would need to be capable of compiling, and actually compile, an adequate factual record to assess the nature and impact of the private conduct in question. The precise factual record that would be required would depend on the substantive norm that the State has provided; the critical question is whether the record has sufficient facts for the reviewing body sensibly to determine that the State's substantive regulatory requirements have been achieved. In the typical case in which the State has articulated a criterion of consumer impact, obtaining reliable, timely, and complete economic data would be central to the regulatory board's ability to determine if the State's chosen criterion has been satisfied.¹⁹ Timeliness in particular is an ongoing concern; if the private conduct is to remain in place for an extended period of time, then periodic state reviews of that private conduct using current economic data are important to ensure that the restraint remains that of the State, and not of the private actors.

In Mississippi, the State had in place rules and regulations pertaining to, and had staff assigned to review, household goods tariffs. In connection with a recent tariff increase request, Respondent sent to the State very general written assertions that movers' costs had increased as well as some assertions regarding specific cost increases. The staff did undertake some review including, for example, checking to see if the cost of packaging material had increased as asserted by movers. In addition, the

¹⁸ *Ticor*, 504 U.S. at 637 (citations omitted).

¹⁹ As the *Ticor* Court held, "state officials [must] have undertaken the necessary steps to determine the specifics of the price-fixing or ratesetting scheme." *Id.* at 638.

Analysis

State monitored Bureau of Labor Statistics printouts giving the national consumer price index and Department of Labor's notices of increases in the national minimum wage.

Nevertheless, Respondent made no showing that the State had done the necessary research into the economic conditions of the moving industry in Mississippi that would enable it to assess the impact of the Respondent's proposal.²⁰ Moreover, there was no showing that the State sought independently to verify the accuracy of the financial information submitted by the movers.²¹

Additionally, in assembling an adequate factual record, the procedural value of notice and opportunity to comment is well established. These procedural elements, which have evolved in various contexts through common law, through state and federal constitutional law, and through Administrative Procedure Act rulemakings,²² are powerful engines for ensuring that relevant

²⁰ Cf. *New England Motor Rate Bureau, Inc.*, 112 F.T.C. 200, 233, 266, 279-80 (1989) (active supervision not found because, *inter alia*, the State had "never conducted an economic study of the intrastate trucking industry nor of the effects of its regulatory policy on the intrastate trucking industry within the state"). Although the First Circuit reversed the Commission's decision, *New England Motor Rate Bureau v. FTC*, 908 F.2d 1064 (1st Cir. 1990), the First Circuit's standard for active supervision was later found to be "insufficient" in *Ticor*. 504 U.S. at 637.

²¹ Cf. *United States v. Southern Motor Carriers Rate Conference*, 467 F. Supp. 471, 477 (N.D.Ga. 1979), *aff'd*, 702 F.2d 543 (5th Cir. Unit B 1983) (active supervision found where, among other things, the State undertook "on-site review and verification of motor carrier books and records"), *rev'd on other grounds*, 471 U.S. 48 (1985).

²² The Administrative Procedure Act defines a rule, in part, as "the whole or a part of an agency statement of general or

Analysis

facts – especially those facts that might tend to contradict the proponent’s contentions – are brought to the state decision-maker’s attention. In Mississippi, the Public Service Commission did give notice to the public that a hearing was to take place to consider increases in rates and it did hold hearings where witnesses testified about their increased costs.²³ For reasons discussed throughout, however, the mere fact of a hearing will not establish active supervision. To show active supervision, Respondent would need to establish that the State takes additional steps to ensure that it makes the rates its own.

B. A Written Decision

A second important element the Commission will look to in determining whether there has been active supervision is whether the state board renders its decision in writing. Though not essential, the existence of a written decision is normally the clearest indication that the board (1) genuinely has assessed whether the private conduct satisfies the legislature’s stated standards and (2) has directly taken responsibility for that determination. Through a written decision, whether rejecting or

particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” 5 U.S.C. § 551(4). Actions “concerned with the approval of ‘tariffs’ or rate schedules filed by public utilities and common carriers” are typical examples of rulemaking proceedings. E. Gellhorn & R. Levin, *Administrative Law & Process* 300 (1997).

²³ See, e.g., August 8, 1995, Notice, Public Service Commission of the State of Mississippi, 95-MC-0329, *In Re: Application of Mississippi Movers Conference Filing Supplement No. 2 to Mississippi Movers Conference Tariff No 2*; October 10, 1995, Public Hearing before the Public Service Commission of the State of Mississippi, 95-MC-0329, *In Re Application of Mississippi Movers Conference Filing Supplement No. 2 to Mississippi Movers Conference Tariff No 2*.

Analysis

(the more critical context) approving particular private conduct that would otherwise violate the federal antitrust laws, the state board would provide analysis and reasoning, and supporting evidence, that the private conduct furthers the legislature's objectives.²⁴

In Mississippi, the State issued written orders granting requests for price increases.²⁵ These written orders simply announced the State's decision. The orders did not discuss evidence supporting the increases nor did they provide the State's analysis or reasoning when the State granted rate increases.

C. Qualitative and Quantitative Compliance with State Policy Objectives

In determining active supervision, the substance of the State's decision is critical. Its fundamental purpose must be to determine that the private conduct meets the state legislature's stated criteria. Federal antitrust law does not seek to impose federal substantive standards on state decision-making, but it does require that the States – in displacing federal law – meet their own stated standards. As the *Ticor* Court explained:

²⁴ A record preserved by other means, such as audio or video recording technology, might also suffice, provided that it demonstrated that the board had (1) genuinely assessed the private conduct and (2) taken direct responsibility. Such an audio or video recording, however, will be an adequate substitute for a written opinion only when it provides a sufficiently transparent and decipherable view of the decision-making proceeding to facilitate meaningful public review and comment.

²⁵ See, e.g., December 19, 1995, Order, Public Service Commission of the State of Mississippi, 95-MC-0329, *In Re Application of Mississippi Movers Conference Filing Supplement No. 2 to Mississippi Movers Conference Tariff No 2*.

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Our decisions make clear that the purpose of the active supervision inquiry is not to determine whether the State has met some normative standard, such as efficiency, in its regulatory practices. Its purpose is to determine whether the State has exercised sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties. Much as in causation inquiries, the analysis asks whether the State has played a substantial role in determining the specifics of the economic policy. The question is not how well state regulation works but whether the anticompetitive scheme is the State's own.²⁶

Thus, a decision by a state board that assesses both qualitatively and quantitatively whether the “details of the rates or prices” satisfy the state criteria ensures that it is the State, and not the private parties, that determines the substantive policy. There should be evidence of the steps the State took in analyzing the rates filed and the criteria it used in evaluating those rates. There should also be evidence showing whether the State independently verified the accuracy of financial data submitted and whether it relied on accurate and representative samples of data. There should be evidence that the State has a thorough understanding of the consequences of the private parties' proposed action. Tariffs, for instance, can be complex, and there should be evidence that the State not only has analyzed the actual rates charged but also has analyzed the complex rules that may directly or indirectly impact the rates contained in the tariff.

If the State has chosen to include in its statute a requirement that the regulatory body evaluate the impact of particular conduct on “competition,” “consumer welfare,” or some similar criterion, then – to meet the standard for active supervision – there should be evidence that the State has closely and carefully examined the

²⁶ *Ticor*, 504 U.S. at 634-35.

Analysis

likely impact of the conduct on consumers. Because the central purpose of the federal antitrust laws is also to protect competition and consumer welfare,²⁷ conduct that would run counter to those federal laws should not be lightly assumed to be consistent with parallel state goals. Especially when, as here, the underlying private conduct alleged is price fixing – which, as the *Ticor* Court noted, is possibly the most “pernicious” antitrust offense²⁸ – a careful consideration of the specific monetary impact on consumers is critical to any assessment of an overall impact on consumer welfare. That consideration should include an express quantitative assessment, based on reliable economic data, of the specific likely impact upon consumers.

It bears emphasizing that States need not choose to enact criteria such as promoting “competition” or “consumer welfare” – the central end of federal antitrust law. A State could instead enact some other criterion. Then, the State’s decision would need to assess whether that objective had been met.

On the other hand, if a State does not disavow (either expressly or through the promulgation of wholly contrary regulatory criteria) that consumer welfare is state regulatory policy, it should address consumer welfare in its regulatory analysis. In claiming the state action defense, a respondent should demonstrate that the state board, in evaluating arguably anticompetitive conduct, had carefully considered and quantified the likely impact of that conduct on consumers as a central element of deciding whether to

²⁷ Indeed, consideration of consumer impact is at the heart of “[a] national policy” that preserves “the free market and . . . a system of free enterprise without price fixing or cartels.” *Id.* at 632.

²⁸ *Id.* at 639 (“No antitrust offense is more pernicious than price fixing.”).

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approve that conduct.²⁹

In the present case, Mississippi has expressly chosen to give significant consideration to, among other state interests, the interests of consumers when determining whether rates are “just and reasonable”:

In the exercise of its power to prescribe just and reasonable rates for the transportation of passengers or household goods . . . the commission shall give due consideration, among other factors, to:

* * * *

the need, in the public interest, of adequate and efficient transportation service by such carriers at the lowest cost consistent with the furnishing of such services.³⁰

Thus, to establish active supervision, Respondent would be obligated to show that the State, when approving the rates at issue, performed an analysis and quantification of whether the rates to consumers were “at the lowest cost consistent with the furnishing of service.” Here, however, Respondent did not produce any substantial evidence that the State had done such an analysis or that the State had adopted a method for evaluating movers’ rates against the statutory criteria.³¹

²⁹ This requirement is based on the principle that the national policy favoring competition “is an essential part of the economic and legal system within which the separate States administer their own laws.” *Id.* at 632.

³⁰ MISS. CODE ANN. § 77-7-211.

³¹ *Cf. United States v. Southern Motor Carriers Rate Conference*, 467 F. Supp. 471, 477 (N.D. Ga. 1979), *aff’d*, 702 F.2d 543 (5th Cir. Unit B 1983) (active supervision established where, among other things, the State reviewed a request for an

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In fact, during one Public Service Commission hearing held to consider movers' request for an increase in rates, a mover opposed the proposed increase on the grounds that he and other movers could continue to profitably move customers at the existing rates.³² The Public Service Commission approved the requested increase in rates without explaining why it rejected this testimony

increase in motor carrier rates by analyzing motor carriers' operating ratios), *rev'd on other grounds*, 471 U.S. 48 (1985).

³² The mover testified as follows:

I think the majority of movers here are making fairly decent money doing this business, some an exception, and I can't answer why because you can make money doing this and there's no problem with that. Any time you buy a box for 50 cents and sell it for \$2.20, you're going to make money on that box.*** I was basically going to say that my company can currently operate profitably based on these rates and provide a good service to the average consumer

I don't know how many of my customers have said, even at church when I'm talking to some of my friends and I tell them how much I sell a box for, they just look at me and say you're robbing us, you're just stealing us blind. And granted this is a hard business to make a profit. I'm not one to make a big profit; I just make a steady living, feed my kids, take care of my house, and give my guys good employment. That's all I do. I'm not out to make a million dollars.

October 10, 1995, Public Hearing before the Public Service Commission of the State of Mississippi, 95-MC-0329, *In Re Application of Mississippi Movers Conference Filing Supplement No. 2 to Mississippi Movers Conference Tariff No 2*, at transcript pages 40, 42, 45.

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or how it decided that the higher rates were at the “lowest cost consistent with the furnishing of [moving] services.”

VI. Opportunity for Public Comment

The standards of active supervision remain those laid out by the Supreme Court in *Midcal* and its progeny. Those standards have been explained in detail above to further illustrate how they would apply should Respondent seek to modify this proposed Order. Applying these standards, the Commission believes, will further the principles of federalism and accountability enunciated by the Supreme Court, will help clarify for States and private parties the reach of federal antitrust law, and will ultimately redound to the benefit of consumers.

These review techniques may also help to show active state supervision in other contexts. In this Analysis we have described particular techniques that can show active supervision in the context of tariff filings. Such filings often involve recurring, concrete acts of private rate setting that tend to automatically trigger review on the occasion of each such filing. As noted above, however, if a rate filing remains in place for a prolonged period of time, the state will have an obligation to review the level of those rates on an ongoing basis. Similarly, there may be other industries where specific events do not trigger a review of private conduct, yet where the state has still displaced competition and therefore the state action defense would apply only where it could be shown that the conduct was being actively supervised. We believe that the review principles described here can be adapted to those circumstances as well. Evidence of active supervision then might be required, not in connection with particular events, but rather on a reasonable periodic basis. That supervision might still involve the elements discussed here, such as notice, analysis in light of the statutory purposes, and a written decision.

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the

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public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or to modify their terms in any way.

Commission Opinion

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION, ET AL.OPINION OF THE COMMISSION AND FINAL ORDER IN REGARD TO
ALLEGED VIOLATIONS OF SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket 9297; File No. 9910256**Complaint, March 30, 2001--Decision, December 8, 2003*

In a unanimous Opinion, the Commission addressed (1) an agreement between Respondent Schering-Plough Corporation and Respondent Upsher-Smith Laboratories, Inc. that, among other things, Upsher-Smith would not market any generic version of Schering's K-Dur 20 product --an extended-release microencapsulated potassium chloride product used to treat patients with low potassium or hypokalemia -- until September 2001, and (2) an agreement between Respondent Schering-Plough and Respondent American Home Products Corporation ("AHP") that, among other things, AHP would not market any generic version of Schering's K-Dur 20 before January 2004. The Commission concluded that both agreements violated Section 5 of the Federal Trade Commission Act. The Final Order, among other things, prohibits the respondents -- in connection with the Sale of Drug Products (as defined by the Order) -- from being a party to any agreement resolving or settling a patent infringement claim, with certain exceptions, in which (A) an Abbreviated New Drug Application ("ANDA") filer receives anything of value and (B) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.

Participants

For the Commission: *Karen G. Bokat, Bradley S. Albert, Elizabeth R. Hilder, Michael B. Kades, Philip Eisenstat, Markus H. Meier, Judith A. Moreland, Melvin H. Orlans, Philip Eisenstat, and David R. Pender.*

For the Respondents: *John W. Niels, Jr., Laura S. Shores, Marc G. Schildkraut, Howrey Simon Arnold & White, and Robert D. Paul, J. Mark Gidley, and Christopher M. Curran, White & Case LLP.*

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OPINION OF THE COMMISSION

By LEARY, Commissioner, For A Unanimous Commission:

I. Introduction and Statement of Issues

This challenging case raises important policy issues at the intersection of patent law and antitrust law. It involves the settlement of patent litigation between the manufacturer of a patented drug and two would-be generic competitors, in the context of the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), 21 U.S.C. § 355 (2001). This statute, passed in 1984, was intended to facilitate earlier entry by the manufacturers of generic drugs (the “generic”), and thereby reduce average prices paid by consumers. At the same time, Congress wanted to preserve incentives for continued innovation by research-based pharmaceutical companies (the “pioneer”).¹

The legislative compromise modified the risks and incentives in patent litigation for both pioneer and generic manufacturers. Among other things, the compromise made it possible for a generic to challenge a pioneer’s patent before the generic actually enters the market, with significantly less exposure to risk of a large damage verdict if the patent is successfully defended. On the other hand, the pioneer can get an automatic stay of up to 30 months – in effect a “preliminary injunction” – without meeting the burden of proof required in a customary patent challenge.

The predictable result has been an increase in pioneer/generic patent litigation and an increase in litigation settlements. The Commission has studied litigation under Hatch-Waxman in some

¹ H.R. Rep No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

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depth,² and has challenged other settlements as anticompetitive.³ A common theme of these challenges has been that particular settlement terms delayed generic entry that otherwise would have been likely to occur. The other cases were resolved by consent orders, however, and this is the first time the Commission has addressed pioneer/generic patent settlements with the benefit of a full administrative trial and record. Notwithstanding the novelty of some issues, we have been able to examine and analyze that record under established antitrust and economic principles.⁴

The Initial Decision dismissed the complaint. After a *de novo* factual and legal review, we reverse and enter an order.

A. The Complaint

The Commission complaint, issued on March 30, 2001, charged that Respondents Schering-Plough Corporation (“Schering”), Upsher-Smith Laboratories, Inc. (“Upsher”) and American Home Products Corporation (“AHP”) violated Section

² Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>.

³ *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), *complaint available at* <<http://www.ftc.gov/os/2000/05/c3945complaint.htm>>; *Geneva Pharm., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), *complaint available at* <<http://www.ftc.gov/os/2000/05/c3946complaint.htm>>; *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), *complaint available at* <<http://www.ftc.gov/os/2000/03/hoechstandrxc.complaint.htm>>.

⁴ In addition, as discussed below, we have had the benefit of a number of judicial opinions that specifically address settlements of patent litigation under Hatch-Waxman processes.

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5 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45, by entering into agreements to delay the entry of low-cost generic competition to Schering’s prescription drug K-Dur 20.⁵

⁵ This opinion uses the following abbreviations for citations:

Comp. - Complaint
ID - Initial Decision of the Administrative Law Judge
IDF - Numbered Findings of Fact in the Initial Decision
CX - Complaint Counsel Exhibit
SPX - Schering-Plough Exhibit
USX - Upsher-Smith Exhibit
JX - Joint Exhibit
Tr. - Transcript of Testimony before the Administrative Law Judge
IH - Transcript of Investigational Hearing
Dep. - Transcript of Deposition
App. Br. - Appeal Brief of Counsel Supporting the Complaint
Schering Ans. Br. - Schering-Plough Answering Brief
Upsher Ans. Br. - Upsher-Smith Answering Brief
Rep. Br. - Reply Brief of Counsel Supporting the Complaint
O.A. - Transcript of Oral Argument on Appeal

References to investigational hearing or deposition transcripts included in the trial record as exhibits are made using the exhibit number with the witness’s name and type of interview provided in parentheses (CX 1511 (Kapur dep.)).

The Appendix to this opinion identifies the witnesses and other people referenced in the opinion.

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1. The Agreement Between Schering and Upsher

Schering sells two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10,⁶ which are used to treat patients with low potassium or hypokalemia. Both products are covered by a formulation patent, which expires on September 5, 2006. In August 1995, under procedures established by the Hatch-Waxman Act, Upsher filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) to market Klor Con M20, a generic version of Schering’s K-Dur 20. This abbreviated procedure allows a generic manufacturer to avoid the duplication of expensive safety and effectiveness studies, so long as it proves that its drug is bioequivalent to the pioneer manufacturer’s already approved drug product. As part of this application, however, the generic must provide certain assurances about patents that claim the referenced drug or a method of using it. Upsher certified that Schering’s patent was either invalid or not infringed by the Upsher product, a so-called “Paragraph IV” certification. Upsher subsequently notified Schering of this application and certification, as required by the Act.⁷

Schering then sued Upsher for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995. Under Hatch-Waxman, this lawsuit triggered an automatic waiting period of up to 30 months for final FDA approval of Upsher’s product. On June 17, 1997, on the eve of trial, Schering and Upsher settled their patent litigation. The automatic 30-month stay was still in effect but would expire in a

⁶ The number in the product names refers to dosage strengths: the “20” tablets contain twice as much potassium as the “10” tablets. Russo, Tr. 3415.

⁷ These procedures are spelled out in 21 U.S.C. § 355(j). The significance of the Hatch-Waxman Act in the antitrust analysis will be discussed below.

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year, at the latest. In this settlement agreement, Schering agreed to make payments totaling \$60 million to Upsher and Upsher agreed not to enter the market with any generic version of Schering's K-Dur 20 before September 2001, over four years later. As part of the settlement agreement, Upsher also licensed Schering to market six Upsher products in prescribed territories.⁸ Among other things, the complaint asserts that Schering's \$60 million payment was unrelated to the value of these Upsher products, but rather was an inducement for Upsher's agreement to defer generic entry.

The complaint charges that Schering and Upsher violated Section 5 of the FTC Act by agreeing that Upsher would "not compete by marketing any generic version of Schering's K-Dur 20 until September 2001." Comp. ¶ 68. It states that this agreement "unreasonably restrains commerce," and thus invokes the standards of Section 1 of the Sherman Act. Comp. ¶¶ 68, 69. The complaint further invokes the standards of Section 2 of the Sherman Act, by charging that Schering "engaged in conduct intended to unlawfully preserve . . . [its] monopoly power" and that it "conspired . . . [to] monopolize." Comp. ¶¶ 70, 71.

In its prosecution of this case, Complaint Counsel argued that the settlement amounted to a horizontal agreement between the pioneer competitor (Schering) and a potential generic competitor (Upsher) that the potential competitor would defer entry, in return for the payment of money by the pioneer to the generic (sometimes referred to as a "reverse payment"). Counsel claimed

⁸ The products are Niacor-SR, Klor Con 8, Klor Con 10, Klor Con M20, Prevalite, and Pentoxifylline. CX 348.

⁹ The payment is characterized as "reverse" because it flows from the pioneer to the generic, unlike the more common provisions of a patent litigation settlement where the alleged infringer pays royalties to the patent holder in exchange for a license.

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that this conduct was either *per se* illegal or subject to condemnation in a truncated proceeding.

2. The Agreement Between Schering and American Home Products

In December 1995, ESI Lederle Inc. (“ESI”), a division of American Home Products Corporation, also submitted an ANDA to the FDA to market a generic version of Schering’s K-Dur 20, with its own Paragraph IV certification. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996. This case was settled in principle by AHP and Schering in January 1998 and the final agreements were concluded in June of that year. As part of this settlement, AHP agreed that it would not market any generic version of Schering’s K-Dur 20 before January 2004, and Schering agreed to make payments totaling \$30 million. Schering also licensed two products from AHP.¹⁰

The complaint’s characterization of the Schering/AHP agreements parallels its characterization of the Schering/Upsher agreement. The complaint states that the Schering payments were not related to the value of the licenses, and thus induced AHP to agree to the delay of its own generic product.

As noted above, AHP was named as a respondent when the Commission issued the complaint in this matter. Before the Commission’s case came to trial, however, AHP agreed to a settlement, and the Commission approved a final consent order with AHP in April 2002. The legality of the agreement between Schering and AHP remains in issue, however, with respect to Schering.

¹⁰ The products are enalapril and buspirone. CX 480.

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B. The Defenses

Both Schering and Upsher denied that their settlement agreement was unlawful and argued additional defenses, which may be summarized as follows.

First, Respondents state there is no proof that the settlement agreement delayed the entry of generic competition for K-Dur 20. Schering's patent, which must be presumed to be valid, did not expire until September 2006, five years after the agreed-upon entry date. They argue that there is no way to know whether generic entry would have been possible at an earlier date in the absence of proof on the merits of the patent litigation.

Second, Respondents state that any assumed agreement on entry was ancillary to a legitimate, procompetitive objective, namely, the settlement of patent litigation. This settlement preserved public and private resources, and the resultant certainty ultimately led to more intense competition.

Third, Respondents state that the \$60 million payment to Upsher was not a payment for delayed entry but rather reasonable compensation for the side agreement involving the six products that Upsher licensed to Schering.

Respondent Schering similarly denies that the AHP agreement was unlawful and relies on the same defenses related to patent validity and the procompetitive benefits of a litigation settlement. Schering also asserts that the agreement was crafted in response to intense judicial pressures for settlement.

C. The Initial Decision

On June 26, 2002, after a two-month trial, the Administrative Law Judge dismissed the complaint in an Initial Decision that contains 121 pages and 431 numbered findings of fact. We disagree with many of the factual and legal conclusions in the Initial Decision. Notwithstanding the complexity of this matter, it

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is possible to identify two fundamental legal errors in the Initial Decision that led ultimately to an erroneous conclusion.

First, the Initial Decision asserted that Schering's patent gave it the legal right to exclude a generic competitor from the market, absent proof that the patent was not valid or that the generic products did not infringe. Since Complaint Counsel did not prove either invalidity or non-infringement, the Initial Decision assumed it was not possible to conclude that the settlement agreements in issue delayed generic entry that would otherwise have occurred. ID at 4, 103-05. This conclusion is incorrect.

The Respondents did not dispute that there were separate agreements between the pioneer, Schering, and two generic competitors, Upsher and AHP, to settle two patent cases. It is also not disputed that these agreements included provisions that provided for unconditional payments from the pioneer to the two generics and also specified the time of generic entry. The issue is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments. We explain below why this question can be answered without an inquiry into the merits of the patent litigation.

Second, the Initial Decision assumed that Complaint Counsel had to prove a "relevant product market," under a traditional full-blown rule-of-reason analysis. The Initial Decision rejected Complaint Counsel's argument that market definition is not necessary when direct evidence of anticompetitive effects can be shown. ID at 4, 84-85. This ruling is also incorrect.

We follow the Supreme Court's guidance, as expressed in the *California Dental* case,¹¹ and explained at length in the

¹¹ *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

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Commission's recent *PolyGram Holding* opinion.¹² The appropriate antitrust analysis extends over a continuum, ranging from *per se* condemnation of particularly egregious conduct to a detailed examination of more ambiguous behavior, responsive to the facts of individual cases. Here, we will need to undertake a more detailed examination of market effects than was required either in *California Dental* or in *PolyGram Holding*, but the guiding principles are the same. We review the agreements in this case under the rule-of-reason standard, but apply a different methodology from that set out in the Initial Decision. We conclude that the Initial Decision's approach – which defines a relevant market, calculates shares, and then draws inferences from these shares and from other industry characteristics – is not the most appropriate way to proceed in cases like this one where more direct evidence of competitive effects is available.

Once Complaint Counsel have demonstrated anticompetitive effects under the standard we apply, Respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible.¹³ Because the Initial Decision concluded that Complaint Counsel had not satisfied their initial burden, it did not separately evaluate Respondents' affirmative justifications outlined in Part I.B. above. We do so.

In addition to these fundamental legal errors, we disagree with the Initial Decision's factual conclusion that the licenses granted to Schering were adequate consideration for the payments made by Schering, and that therefore the payments were not for delay.

¹² *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 at 22,453-58 (FTC 2003), available at <<http://www.ftc.gov/os/2003/07/polygramopinion.pdf>>, slip op. at 13-29.

¹³ See *id.*, 5 Trade Reg. Rep. at 22,458-59, slip op. at 31-32.

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ID at 107-12. Our review of the record compels a contrary conclusion.

The Commission may review *de novo* both the factual findings and the legal conclusions of the Administrative Law Judge. 16 C.F.R. § 3.54(a). This *de novo* review includes findings on the credibility of witnesses.¹⁴ On the basis of the totality of the record evidence, we have made *de novo* findings of fact that differ substantially from those in the Initial Decision. We identify these factual findings specifically and discuss their significance throughout the opinion. We do, however, adopt other findings of fact in the Initial Decision, to the extent they are consistent with this opinion, most specifically those relating to jurisdiction (IDF 1-12) and certain facts about the Schering/AHP agreement (IDF 370-75).

D. Summary and Conclusions

Part II of this opinion discusses the sufficiency of Complaint Counsel's affirmative case. It will set forth in more detail the fundamental elements of the rule-of-reason methodology that we have applied and show that this methodology is consistent with existing authority. We examine the record evidence relating to both the predicted and the actual effects of the entry of generic competition for Schering's K-Dur 20 product, and we make our own factual findings. We find that Complaint Counsel have met their initial affirmative burden.

Part II of the opinion also addresses the Initial Decision's conclusion that it is not possible to determine whether the Schering/Upsher and the Schering/AHP settlements delayed entry

¹⁴ *Horizon Corp.*, 97 F.T.C. 464, 857 n.77 (1981). This general rule is subject to the caveat that an administrative law judge has the opportunity to observe the witnesses in a live setting, but no findings of the Initial Decision in this case were based specifically on the demeanor of a witness on the stand.

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unless we first decide the merits of the underlying patent disputes. We find that this requirement is not supported by law or by logic.

In Part III of the opinion, we address Respondent's affirmative defense that the agreement between Schering and Upsher was ancillary to the legitimate settlement of a patent dispute. We recognize that litigation settlements can conserve public and private resources and create other efficiencies. This does not mean, however, that all settlements are procompetitive, and we find that there is insufficient evidence to support the defense in this case.

In Part IV of the opinion, we address at length the claims that Schering paid Upsher \$60 million for licenses rather than for delay. Our conclusion – based on the cumulative impact of numerous documents, conversations and events – is that there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry, and that this payment substantially exceeded Schering's reasonable expectation of the value of the Upsher licenses. The details of this particular case-specific issue may not be of the same general interest as other matters discussed in Parts II and III of the Opinion, and we therefore discuss these other matters before we consider the facts on the valuation of the licenses.

In Part V, we separately discuss the particular facts and legal analysis of the Schering/AHP agreement. There is far less record evidence on this agreement but we apply the same methods of analysis and reach the same conclusions as we have done earlier with respect to the Schering/Upsher agreement. In Part VI, we explain why it is not necessary or appropriate to address the monopolization counts. In Part VII we explain why we need not rule on certain evidentiary matters.

In conclusion, after a *de novo* review of the record, we reject many of the findings of fact in the Initial Decision and substitute our own findings, and we further reverse the ultimate decision to dismiss the complaint. We find that both the Schering/Upsher and

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the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. We conclude that there is sufficient proof of adverse competitive effects; that it is not necessary to inquire into the merits of the underlying patent disputes; that the parties have not proved their ancillarity defenses; and that the payments from the pioneer to the generics were, in whole or in substantial part, consideration for delay rather than for products licensed from the generic.

Accordingly, we reverse the Initial Decision and enter an appropriate order, which is discussed in Part VIII. We note here that the order does not prohibit all settlement agreements that specify a generic entry date coupled with the payment of “value” to the generic, but excepts payments that are limited to litigation costs up to \$2 million if the Commission has been notified of the settlement.

II. The Sufficiency of Complaint Counsel’s Affirmative Proof

A. Complaint Counsel’s Initial Burden

The essence of Complaint Counsel’s claim is that Schering agreed to pay Upsher some part of \$60 million in return for Upsher’s agreement to defer the launch of its generic product.¹⁵ It is undisputed that there was an agreement that specified a future entry date and that money was paid. There is, however, a dispute over the competitive impact of the agreement and the appropriate legal standard to apply when resolving that issue.

The Commission recognized in *PolyGram Holding* that once an “agreement” has been proved, the prosecutor’s initial burden

¹⁵ Similar claims with respect to Schering’s settlement with AHP will be discussed separately in Part V.

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varies according to the individual facts of the case.¹⁶ We do not focus on labels but on the question of which party has the burden of producing what kind of evidence and when.¹⁷ *PolyGram Holding* involved conduct that we called “inherently suspect.”¹⁸ In that kind of case, the focus is on the nature of the *restraint*, and the likelihood of competitive harm is readily apparent or can “easily be ascertained.”¹⁹ A prosecutor’s initial burden can be satisfied by showing that anticompetitive effects are likely, on the basis of “past judicial experience and current economic learning.”²⁰

In cases like this one, where the conduct is not inherently suspect, the prosecutor has the burden of demonstrating actual or likely market effects by reference to facts specific to the case. However, proof of these effects does not necessarily mandate the approach followed in the Initial Decision – namely, an effort to define the “relevant market” coupled with an effort to balance an undifferentiated set of factors like those listed in *Brown Shoe v.*

¹⁶ *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,466 n.66, slip op. at 49 n.66.

¹⁷ A preoccupation with labels can lead, at the extreme, to an essentially meaningless distinction between *per se* analysis and rule-of-reason analysis that is completed in “the twinkling of an eye.” Phillip E. Areeda & Herbert Hovenkamp, 7 Antitrust Law ¶ 1508a, at 391 (2003). We believe that the structure, outlined here and in our *PolyGram Holding* opinion, reflects a growing recognition of the limitations of semantics.

¹⁸ *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,456, slip op. at 22-23.

¹⁹ *California Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

²⁰ *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,459-60, slip op. at 29.

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United States.²¹ As will appear in the detailed discussion of the evidence that follows, more direct methods are available and are preferable.²²

In this case, Complaint Counsel made an alternative argument that the settlement agreements in issue should be characterized as either *per se* illegal or presumptively anticompetitive.²³ Translated into the terms of the structure outlined above, their claim was that the nature of the restraint is sufficiently troublesome to obviate specific proof of market effects.

There is some logical and legal support for this proposition. The essence of the complaint is that the pioneer paid the generics not to compete for a period of time, which could be *per se* illegal in other contexts. Absent a legitimate business justification,²⁴ naked agreements between competitors to allocate business by customers or geographic areas are routinely condemned out of hand. See, e.g., *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593

²¹ *Brown Shoe Co. v. United States*, 370 U.S. 294, 321-22 (1962).

²² The distinction between indirect and direct proof of market effects is not related to the sheer quantity of evidence that a prosecutor needs to introduce. Direct proof of competitive effects, on which we rely in this case, is not the same as a truncated analysis that would be appropriate in those cases where the nature of the restraint dominates. Direct proof is not necessarily a shortcut method; it is rather a method that relies on the most probative available evidence.

²³ App. Br. at 40, 70.

²⁴ As articulated in the recent *PolyGram Holding* opinion, a legitimate business justification must be both plausible and cognizable. 5 Trade Reg. Rep. at 22,459, slip op. at 30-32.

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(1951). We believe that a naked agreement to pay a potential competitor to delay its entry date could logically be treated the same way because an allocation of time is analogous to an allocation of geographic space. The effects of horizontal agreements to allocate business are well understood, and it is not imperative for the Commission or a court to have firsthand experience with the practice in a specific industry context.²⁵

There is also recent authority in the same industry to support a claim of *per se* illegality. In the *Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), the court found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry. The current trend of authority seems to be moving in another direction, however.²⁶ The even more recent decisions in *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, 344 F.3d 1294 (11th Cir. 2003) (reversing the district court), and in the *Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188

²⁵ Cf. *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 350-51 (1982) (*per se* rule does not have to “be rejustified for every industry that has not been subject to significant antitrust litigation”).

²⁶ The *Cardizem* case also can be distinguished on its facts. In *Cardizem*, there were additional potentially anticompetitive commitments by the generic that are not present here. Unlike the present case, *Cardizem* involved an interim rather than a final settlement, so it would be more difficult to claim that the agreement was ancillary to an efficient disposition of the litigation. The opinion did not need to consider a claim that the generic was paid by the pioneer for licenses rather than for delayed entry. We also do not believe the opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach. See, e.g., *California Dental Ass’n v. FTC*, 526 U.S. 756 (1999); *National Collegiate Athletic Ass’n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984).

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(E.D.N.Y. 2003), expressly considered contrary authority and declined to apply the *per se* label. *See also In re Tamoxifen Citrate Antitrust Litig.*, 262 F. Supp. 2d 17 (E.D.N.Y. 2003).

In addition to the crosscurrents in the case law, we recognize – as discussed further below – that agreements of the kind challenged here can be procompetitive in limited circumstances. For example, a settlement that includes payments to a cash-starved generic might, in some circumstances, permit earlier entry than would otherwise occur. We do not believe that special circumstances of this kind have been established here, but the fact that such efficiencies are theoretically possible makes us reluctant to deal summarily with the agreements at issue in this case. *See California Dental Ass’n v. FTC*, 526 U.S. at 777-78.

We note that these and other potential efficiencies are also cited in support of an argument that the challenged agreements are ancillary to the settlement of litigation – an outcome that is claimed to be efficient and procompetitive overall. It is, of course, appropriate to consider an ancillarity claim, even if a particular contract term would be condemned summarily if it stood alone;²⁷ therefore, the mere existence of an ancillarity claim does not determine the form of analysis that should be applied. However, Respondents’ claim here is that the challenged agreements were ancillary to the settlement of *patent* litigation. The fact that “one of the parties owned a patent . . . [which] grants its owner the lawful right to exclude others” was a complicating factor which induced the *Valley Drug* court to reject a *per se*

²⁷ *See, e.g., Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1033 (1987); United States Dep’t of Justice and Federal Trade Comm’n, Antitrust Guidelines for Collaborations Among Competitors, § 3.2 (2000), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,161, *available at* <<http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>>.

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standard. *Valley Drug*, 344 F.3d at 1304-06.²⁸ The existence of claimed patent rights was also a dispositive fact for the Administrative Law Judge in this case. ID at 4, 103-04.

We believe that it is necessary to recognize that patent issues exist as we address Complaint Counsel's initial burden of proof, and the issues cannot be resolved in a summary way – at least, not in this case of first impression for the Commission. Instead, we need to explain the reasons why the merits of the underlying patent claims are not dispositive. We also need to address the particular competitive significance of generic substitutes for patented drugs, as evidenced by economic studies, by the expectations of firms in the market, and by actual market events.

In this case, we will apply and build on fundamental principles that were discussed at length in *PolyGram Holding* – a Commission opinion that was itself based on a synthesis of recent Supreme Court decisions. Our *PolyGram Holding* opinion explains that bright-line distinctions are normally not particularly helpful; the appropriate methods of analysis extend over a continuum. This case differs from *PolyGram Holding*, however, not because the principles are different, but because it occupies a different place along the continuum. While a “scrutiny of the restraint itself” was sufficient in *PolyGram Holding*,²⁹ the facts of this case require us to look beyond the nature of the challenged restraint and consider the nature of the market. As noted above,

²⁸ See also *Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 249 (“[T]he exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal.”).

²⁹ 5 Trade Reg. Rep. at 22,458, slip op. at 29. We leave open the question whether it would be appropriate to apply this test in a future case that involved a patent settlement with payments from the pioneer to the generic manufacturer that appear to be substantially larger than reasonably anticipated costs of litigation.

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this market inquiry differs from the inquiry outlined in the Initial Decision.

B. The Evidence in Support of Complaint Counsel's Case

Complaint Counsel's affirmative case was based on an economic model, buttressed by contemporaneous records. The lead witness was an economic expert, Professor Timothy F. Bresnahan, who relied on the following three-prong test to determine whether the Schering patent settlements were anticompetitive.

First: Did Schering have "monopoly power" in the market for K-Dur 20?

Second: Were generics a threat to this monopoly power?

Third: Did Schering make a payment to defer generic entry?

Bresnahan, Tr. 418-19.

Although we rely on Professor Bresnahan's testimony in part, we do not adopt his terminology. We are here concerned with whether a particular agreement was, in the language of the Sherman Act, a prohibited "restraint of trade." See *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289 (1985). It is obviously necessary to identify the "trade" that arguably has been unreasonably restrained, but this identification is not the same thing as defining a legal "market" that can be "monopolized."³⁰ As explained in more detail below, it is not necessary to rely on indirect proof that Schering has a monopoly share in a relevant market when the competitive effects

³⁰ The Initial Decision fails to appreciate this distinction, when it says that "Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected." ID at 85-86. The products affected by the challenged conduct were clearly identified.

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of the “restraint” can be shown directly.³¹ Moreover, in the circumstances of this case, the first two prongs of the Bresnahan test really depend on the same evidence, because the particular significance of generic entry is what actually defines the appropriate area of trade to consider. This particular significance drives the Hatch-Waxman regulatory scheme, and is recognized in the Respondents’ internal documents and in the arguments of their counsel. Conversely, the third prong of the Bresnahan test really involves consideration of two separate issues, namely, (i) the rationale for focusing on whether there was a payment by Schering, and (ii) whether Schering, in fact, paid money for deferred entry. Resolution of this latter issue requires detailed factual discussion, contained in Part IV of this opinion.

1. The Competitive Effects of Generic Entry

Most cases that are not resolved by a summary analysis begin with the definition of a “relevant market,” under various tests sanctioned by case law or by agency guidelines, followed by the calculation of the sales shares of various players and concentration ratios, and conclude with an evaluation of various industry-specific factors. *See, e.g., Brown Shoe Co. v. United States*, 370 U.S. 325 (1962); *FTC v. H.J. Heinz Co.*, 246 F.3d 708 (D.C. Cir. 2001); U.S. Dep’t of Justice & Federal Trade Comm’n, *Horizontal Merger Guidelines* (1992), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,104 (“Horizontal Merger Guidelines”). In this case, the Administrative Law Judge found that Complaint Counsel had not proved their case in the traditional way, and viewed this failure as a fatal flaw. ID at 84-95. We disagree, and hold that the Initial Decision misstates the requirements for proof of a violation when a summary analysis is inappropriate.³²

³¹ *See FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 460 (1986).

³² The error is perhaps understandable because some in the antitrust community have become so accustomed to the traditional

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There are a variety of ways to analyze market impact under the rule of reason. In *FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 460-61, the Supreme Court said that “the finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis.” A number of lower court decisions have followed this principle. See, e.g., *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) (evidence of “an actual adverse effect on competition . . . arguably is more direct evidence of market power than calculations of elusive market share figures”); *Toys “R” Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (market power can be proved “through direct evidence of anticompetitive effects”); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 992 (D.C. Cir. 1990) (“[m]arket share is just a way of estimating market power, which is the ultimate consideration,’ and . . . ‘[w]hen there are better ways to estimate market power, the court should use them” (quoting *Ball Mem'l Hosp. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1336 (7th Cir. 1986))).

The Initial Decision briefly acknowledges Complaint Counsel’s reliance on *Indiana Federation of Dentists* for the proposition that direct proof of anticompetitive effects is sufficient. The Initial Decision concludes that no such direct effects were proven because Complaint Counsel’s expert did not conduct elaborate price studies. ID at 91. However, *Indiana Federation of Dentists* did not say that price studies are necessary to prove direct anticompetitive effects. On the contrary, the Supreme Court found:

A concerted and effective effort to withhold (or make more costly) information desired by consumers for the purpose of

way of proceeding that they forget that this complex market analysis provides only an *indirect* indication that trade has been or may be restrained. It is not necessary to weigh all of these factors if a case presents more *direct* evidence of actual or likely competitive effects.

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determining whether a particular purchase is cost justified is likely enough to disrupt the proper functioning of the price-setting mechanism of the market that it may be condemned *even absent proof that it resulted in higher prices or . . . the purchase of higher priced services than would occur in its absence.*

FTC v. Indiana Fed'n of Dentists, 476 U.S. at 461-62 (emphasis added). The justification for use of direct evidence in this case is even stronger than it was in *Indiana Federation of Dentists* because the predicate offense was not just an effort to withhold useful information, but rather an agreement to defer entry by a potential competitor.

Similarly, the Seventh Circuit did not require price studies to find anticompetitive effects in *Toys "R" Us, Inc. v. FTC*. The court concluded that horizontal agreements that limited the distribution of particular toys to a class of retailers had obvious price effects, but did not detail what they were:

[I]t was clear that [Toys "R" Us's] boycott was having an effect in the market. It was remarkably successful in causing the 10 major toy manufacturers to reduce output of toys to the warehouse clubs, and that reduction in output protected TRU from having to lower its prices to meet the clubs' price levels. Price competition from conventional discounters . . . imposed no such constraint. . . . Taking steps to prevent a price collapse through coordination of action among competitors has been illegal at least since *United States v. Socony-Vacuum Oil Co.* Proof that this is what TRU was doing is sufficient proof of actual anticompetitive effects that no more elaborate market analysis was necessary.

221 F.3d at 937 (citations omitted).

The Commission itself very recently explained in the *PolyGram Holding* opinion that "the evaluation of horizontal

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restraints takes place along an analytical continuum in which *a challenged practice is examined in the detail necessary to understand its competitive effect.*” *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,456, slip op. at 22 (emphasis added).³³ We will apply this approach as we evaluate the evidence of competitive effects that was submitted as part of Complaint Counsel’s case.³⁴

It is important to remember what this case is and is not about. If we were evaluating the potential effects of a merger between Schering and another manufacturer of potassium chloride supplements that are functionally interchangeable with Schering’s K-Dur 20, a broad market definition encompassing all prescription oral potassium supplements, which the Administrative Law Judge adopted in this case (ID at 87, citing IDF 29-118), might well be appropriate. This hypothetical merger might have some effect on the sales or prices of K-Dur 20, and it might have a more profound effect on innovation in the therapeutic category, even though the looming threat of future generic competition could ultimately transform the market entirely. A merger that threatens competition in some substantial respect is not necessarily benign just because more substantial threats exist.

This case, however, is precisely concerned with that more substantial threat of generic competition, and there is credible evidence in the record – largely ignored in the Initial Decision – which indicates that generic entry was a uniquely significant

³³ This statement is supported directly by the Supreme Court’s observation in *California Dental* that “[w]hat is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.” *California Dental Ass’n*, 526 U.S. at 781.

³⁴ As stated above, the effects of the restraint involved in *PolyGram Holding* did not require the same market analysis as the restraint involved in this case.

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market event, and recognized as such by both parties. Their predictions about the likely effects of generic entry, which were consistent with historic experience of other branded drugs, are just as compelling as predictions based on market shares. Moreover, these predictions turned out to be true. We therefore analyze that evidence in some detail, and set forth our own findings of fact and legal conclusions in the immediately following paragraphs. Because we have concluded that the Initial Decision's treatment of the "market" issue is inappropriate for this case, we do not adopt the Initial Decision's voluminous factual findings on the issue.³⁵

2. Findings of Fact on the Competitive Effects of Schering's Agreement With Upsher

At the time of the agreement, both Schering and Upsher expected that generic entry would have a substantial impact on Schering's sales. Upsher's Klor Con M20 would have been (and eventually was) the first "AB-rated"³⁶ generic substitute for K-Dur 20. Easy substitutability at the pharmacy level, combined with state substitution mandates and managed care incentives,³⁷ would

³⁵ We do not reject the findings (IDF 25-118) because they are erroneous but because they are not relevant to our legal analysis of the challenged settlement agreement.

³⁶ Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. Hoffman, Tr. 2278.

³⁷ In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at ¶ 18. A pharmacist cannot substitute a generic that is not AB-rated for a branded drug without the physician's approval. Bresnahan, Tr. 491; Russo, Tr. 3468. In some states, pharmacists are required to substitute an

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have caused Schering to lose rapidly a large volume of its sales to Upsher's lower-priced generic substitute. The entry of a lower-cost generic is a direct consumer benefit, by itself, wholly apart from the impact on other potassium chloride supplements. A settlement with Upsher that provided for delayed entry of this lower-cost generic product would enable Schering to maintain its sales of, and profits from, K-Dur 20 for a considerable period of time – but at significant cost to consumers. Schering's anticipated loss of sales because of generic entry provides an indication of the magnitude of the settlement's anticompetitive effects.³⁸

Schering's 1997 Operating Plan, dated November 11, 1996, clearly shows that Schering expected that generic entry would dramatically erode K-Dur sales in 1998 and 1999. K-Dur sales revenues were projected to fall by 17% in 1998 and an additional 33% in 1999 from the sales levels estimated for 1997. CX 118 at SP 2300218aa. Similarly, an internal Schering analysis in June 1997, before the settlement agreement, predicted that total K-Dur revenues would drop from \$190 million in 1997 to \$113 million in 2000, and to \$70 million in 2001. CX 750 at SP2300307aa; *see also* CX 123 at SP004811 (*in camera*). The settlement, which deferred the threat of generic entry, significantly altered Schering's K-Dur forecasts. The 1998 Operating Plan – dated November 14, 1997, after the settlement with Upsher – shows

AB-rated generic unless the physician directs otherwise. Bresnahan, Tr. 1178; Addanki, Tr. 5998. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93.

³⁸ The magnitude of the expected impact on average prices can be calculated from Respondents' own internal estimates. *See* discussion below.

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projected increases in K-Dur sales each year through 2000.³⁹ CX 118 at SP2300218aa-219aa.

Upsher's predictions were similar. An April 1992 analysis predicted that its entry (assumed to occur in late 1997) would reduce K-Dur 20 revenues from \$184 million in 1997 to \$122 million in 1999.⁴⁰ This Upsher document predicts the effects of its entry on total 20 mEq revenues for all manufacturers, namely, a drop from \$184 million in 1997 to \$148.5 million in 1999 (a 19% decline), even as the total number of tablets sold was expected to increase from 560 million in 1997 to 665 million in 1999 (a 19% increase). CX 150 at USL08538.⁴¹ A simple calculation indicates that the weighted average price per tablet was expected to decline more than 30 percent, from 33 cents to 22 cents.⁴²

AHP's predictions were [redacted from public record version].

³⁹ Sales of K-Dur 10 and K-Dur 20 are combined in these documents. K-Dur 20 accounted for 86% of total K-Dur sales during 1997. CX 62.

⁴⁰ Upsher anticipated revenues of \$16 million in 1999 from sales of Klor Con M20, and expected that another generic (likely Warrick) would earn \$10.5 million. CX 150 at USL08538.

⁴¹ Also, during the negotiations with Schering, Upsher sought \$60-70 million based on its calculation of Schering's lost profits due to earlier entry. Hoffman IH at 35; Hoffman, Tr. 3544; Driscoll IH at 67. AHP made a similar demand. CX 1508 at 99-100 (Hoffman IH); *see also* Rule, Tr. 2583-84 (addressing antitrust implications of payments based on lost profits of pioneer).

⁴² Upsher expected its own Klor Con M20 and another "20" product to be priced at 50% of Schering's price per tablet and the average selling price of Schering's K-Dur 20 to fall 20% due to competition. CX 150.

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The expectations of both Respondents and AHP are consistent with the impact on brand-name pharmaceutical sales generally observed upon entry of the first generic competitor. Studies by the Congressional Budget Office (“CBO”) and economists have explored this phenomenon,⁴³ and all have reached similar conclusions about the impact on sales and average prices. The CBO study,⁴⁴ for example, looked at 21 drugs that first encountered generic competition between 1991 and 1993. After one year, these drugs had lost an average of 44% of sales revenue (and 42.8% of prescriptions) from drugs dispensed through pharmacies to their generic counterparts. The CBO study also found that the retail price of the generic drugs was 25% less than that of the brand-name drugs, on average. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at 28 (July 1998); see also Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 89 (1997) (“The substantial shift in market share from brand-name to generic producers (40%-50%) along with the significantly reduced price of generic substitutes (25%-30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen.”); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & Econ. 331, 335 (1992) (the “general pattern is that generics enter at a significant discount to the pioneering product [and] . . . the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms”);

⁴³ Our opinion is not predicated on these studies standing alone. We rely on Respondents’ own analyses, but we note that economic literature consistently shows that generic entry lowers overall average prices significantly in this industry.

⁴⁴ Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

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“[a]verage market price [weighted by sales of the brand and generic] declined by a little more than 10 percent per year in the first two years after generic entry”); Richard E. Caves, *et al.*, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics 1 (1991) (analysis found that the price of the first generic producer is about 40% below the pre-patent expiration branded price of the drug).

The actual decline in K-Dur sales following the September 2001 entry of Upsher’s Klor Con M10 and Klor Con M20 is also consistent with the expectations of both Respondents and AHP. When Upsher entered the market, its generic product was priced at approximately 50% of the price of K-Dur 20. Rosenthal, Tr. 1559. The impact on Schering’s K-Dur 20 sales was dramatic: total prescriptions fell from 1,158,000 in November 2000 to 391,000 in November 2001. Schering’s lost sales of 767,000 prescriptions are almost precisely offset by the sales of 703,000 prescriptions of new generic versions of K-Dur.⁴⁵ (Prescriptions for Upsher’s generic version were 639,000 and Warrick’s were 64,000, up from zero the previous year.⁴⁶) During the same

⁴⁵ In its post-trial brief (Apr. 15, 2002, pp. 92-93), Upsher insists that some unspecified part of the decline in Schering’s sales was due to supply problems. *See also* ID at 99. If this is true, the magnitude of the actual loss of sales overstates the actual harm to competition from the settlement, and an assessment of damages would require us to measure this effect. However, our purpose here is to ascertain liability rather than damages, and the decline in sales is dramatic and consistent with the expectations of the parties. CX 62-65, 1480.

⁴⁶ Warrick Pharmaceuticals Corporation is a subsidiary of Schering that produces generic pharmaceutical products. In some situations, Warrick produces generic versions of Schering’s patented products when another generic version of the drug has entered the market.

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period, the total prescriptions for all potassium chloride products remained roughly constant.⁴⁷ In the years prior to generic entry in 2001, the sales trends for K-Dur 20 had been similar to those for all potassium chloride products.⁴⁸ CX 62-65; *see also* SPX 1123 at AHP 1300115, 1300117. Schering's concerns about generic entry were obviously well founded.

3. Schering's Attempt to Discount These Competitive Effects

Schering advances two arguments in an attempt to explain away the significance of a growth in generic sales at the expense of pioneer sales. Schering argues, first, that part of the generic's sales performance is attributable to state laws that mandate the substitution of lower-priced generic drugs and the fact that payors often insist on such substitution. Schering argues, second, that the sales of its own drug are also adversely affected by the fact that it is common practice in the industry for the pioneer drug manufacturer to cut back on sales promotion efforts after a generic substitute becomes available. Schering Ans. Br. at 72-74. There is obviously a concern that sales promotion will confer a "free riding" benefit on all competitors, but these concerns apparently are magnified for a particularly close competitor like a generic. We accept that the factual predicate for these arguments may well be true, but these facts actually support Complaint Counsel's case rather than Schering's. They merely underscore the well-recognized unique impact of generic competition.

⁴⁷ Total prescriptions were 2,716,000 in November 2000 and 2,758,000 in November 2001. CX 1480 at SP 089837. This pattern of sales might suggest that K-Dur 20 and its generic substitutes were actually in a relevant "market" by themselves, if it were necessary to define a market in this case.

⁴⁸ Evidence of this kind might have a bearing on whether Schering was a monopolist before generic entry, but we do not reach that issue in this case. *See* Part VI, below.

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Generic pharmaceutical competition is conducted in a special legal environment that differs in significant respects from a truly unregulated market place. In addition to state generic substitution laws, competition is affected by the requirement for FDA approval and by the regulatory provisions of Hatch-Waxman. All markets are affected by regulation to one degree or another, however, and these regulations need to be accepted as real market factors in an antitrust analysis – not simply assumed away. If entry were an issue in a merger case, for example, it would be entirely appropriate for a decisionmaker to take into account import restrictions or environmental impediments to expansions of plant capacity.⁴⁹

Moreover, in the case before us, the existence of state substitution laws, as well as payors that mandate substitution on their own, provides an additional argument for treating generic competition as likely to have a particularly substantial impact. The underlying premise of these laws and payor practices is that generic competition has the potential to lower prices, and therefore should be promoted.⁵⁰ The executives of Schering and Upsher who negotiated the settlement in issue must have been aware of these laws and practices, and the effects that they have had in their industry. The internal market predictions of their respective companies take entry into account. It is not unreasonable to assume that, armed with this knowledge, they *expected* Upsher's entry to create the precise competitive threat that actually defines the area of trade we need to focus on here.

Similarly, if drug manufacturers react to generic entry by reducing promotions, as Respondents claim, it is further evidence

⁴⁹ See Horizontal Merger Guidelines §§ 1.43, 3.1.

⁵⁰ See *Andrx Pharms. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001) (“Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.”), quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

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that generic competition by itself has a significant effect. These reactions – along with the reactions of payors and state substitution laws – are consistent with our conclusion that generic competition is the closest substitute and that there is an adverse competitive effect, even though a broad “market” might be defined for another purpose.

Upsher advances still another argument to explain why the introduction of its own generic was so successful. It claims that the delayed entry negotiated in the settlement agreement was actually procompetitive because the company was able to increase its capacity and enter in force on a date certain, with greater market impact. Upsher Ans. Br. at 38-41. This argument appears to be inconsistent with the internal market forecasts, discussed above, which predicted substantial earlier entry. Upsher also does not explain why it needed to delay entry for over three years beyond expiration of the Hatch-Waxman stay. In fact, after the consummation of the agreement, Upsher slowed the pace of its work on the launch of Klor Con M20 and shuffled Klor Con personnel to other projects. Kralovec, Tr. 5094. Work on the launch was suspended for a time, and the new launch team was not gathered until May 1999. Kralovec, Tr. 5094; Gould, Tr. 5116, 5173. Even with this delay, Upsher considered that it was starting this work in ample time for the September 2001 launch. Kralovec, Tr. 5046-47; Gould, Tr. 5116, 5118-19. This suspension may have been a sensible business decision in the circumstances, but it undercuts any argument that a three-year delay was a requisite for substantial entry.

We therefore conclude that there is substantial evidence to support Complaint Counsel’s claim that delayed generic entry in this situation would harm consumers by depriving them of the choice of a lower-cost generic version of K-Dur 20. We now discuss why we believe that Schering’s payment resulted in a greater delay than would otherwise have occurred.

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4. The Particular Significance of Schering's Payment

A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. In light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations.⁵¹ Complaint Counsel's entire case proceeds on the theory that the payment of money by Schering to a potential generic entrant is what makes this case different. As Bresnahan stated:

[W]hat matters is the difference between the amount of competition we got here . . . versus the amount of competition that was likely to occur had it not been for the payment to delay. . . . It's that comparison that matters, not the absolute amount.

⁵¹ The Commission's study of patent settlements under the Hatch-Waxman Act identified a large number of unchallenged agreements where the parties settled on a deferred entry date. The Commission study uncovered two agreements (Drug Products G and H in Chart 3-2) in which generic entry occurred under royalty-free licenses. The large majority of agreements in which generic entry occurred prior to patent expiration involved situations in which the generic applicant paid a royalty to the brand-name company during the remaining patent life (Drug Products A-F in Chart 3-2). Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 29 (July 2002). These particular facts, based on a non-record source of which we take notice, have not been disputed by any of the parties (although Respondents did object to other data in the study). *See* Order Granting Motion for Leave to File Reply Memorandum; Denying Motion to Strike Reliance on FTC Study; and Permitting Each Party to File a Brief Addressing Cited Facts Contained Therein (Jan. 6, 2003).

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Bresnahan, Tr. 614. We agree.

If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration,⁵² it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.⁵³ *Cf. FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 456 (FTC's conclusions supported by "common sense and economic theory, upon both of which the FTC may reasonably rely"); *see also* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *Rand J. Econ.* 391 (2003); Herbert Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 *Minn. L. Rev.* 1719, 1757-61 (2003).⁵⁴ The nexus between payment and delay is supported not

⁵² In this case, of course, Respondents have attempted (but failed) to demonstrate that there were other offsetting considerations adequate to account for the payment. *See* discussion in Parts III and IV, below.

⁵³ This is the first subsidiary issue subsumed in the third prong of Professor Bresnahan's test.

⁵⁴ We are aware of the recent opinion in *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 2003 U.S. Dist. LEXIS 19370 (N.D. Ill. 2003) (Posner, J.), which questioned whether these concerns about reverse payments are based on "a sound theory." *Id.* at *21. Since the comment was made in passing and was admittedly "inapplicable" to the case before the court, we only note it here. To the extent that the court was opposed to *per se* condemnation of reverse payments, we emphasize that we have not applied a *per se* standard in this case and we have acknowledged that there are possible arguments in justification. More broadly, the court seems to be concerned that prohibition of "reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options[.]" *Id.* Any antitrust restrictions

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only by simple logic but also by the plain language of the settlement agreement and the history of the negotiations between the parties. *See* Part IV, below.

According to Bresnahan, there is also a powerful incentive for the contending parties to make these agreements. The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete. It would be mutually beneficial for the patent holder and the challenger to defer entry of the generic and split the patent holder's profit. Bresnahan, Tr. 426-29, 495, 612-13; Goldberg, Tr. 119-20; Kerr, Tr. 6261. The resulting adverse effects on consumers are obvious.

We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences. *Compare Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 591 n.15 (1986) (the Court recognized that *weak* incentives make price predation highly unlikely).

One recent district court decision expresses a different view of incentives, in a lengthy opinion that we need to address. In the *Ciprofloxacin Hydrochloride* case, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), one reason for the court's rejection of a *per se* standard was its conclusion that Hatch-Waxman settlements are "unique" because the statute has distorted the relative bargaining power of the litigating parties. *Id.* at 250-52. In what the court called a "traditional scenario," a party can challenge a patent only by entering the market with its infringing product and risking a

on settlement agreements have the effect of reducing settlement options, but Judge Posner expressly states in the same opinion that some provisions should be condemned. *Id.* at *11-13.

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lawsuit for substantial damages. *Id.* at 251. The court went on to say that the event that triggers litigation under Hatch-Waxman – an ANDA filing with a Paragraph IV certification – is an “artificial act of infringement.” *Id.* This “artificial act” eliminates the generic’s potential exposure to liability for the pioneer’s “enormous losses,” and thus deprives the pioneer of its “traditional leverage” in litigation. *Id.* According to the court, this shift in the relative bargaining power of the parties means that “so-called reverse payments are . . . a natural by-product” of the Hatch-Waxman process. *Id.* at 252.⁵⁵

We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that. However, because of the economic reality that generic entry causes a loss to the pioneer well in excess of the generic’s anticipated profit, and the fact that damages for infringement are based on the *pioneer’s* lost profit, a generic litigant still risks losses well in excess of its anticipated gains. This powerful disincentive for patent challenges may have been “traditional,” but Congress specifically decided that it wanted to encourage patent challenges for pharmaceutical products. (An offsetting concession for patent holders is the automatic 30-month stay.)⁵⁶ As stated above, antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework.

A payment for delayed generic entry under a Hatch-Waxman framework is no less anticompetitive than a similar payment under

⁵⁵ This argument is cited with apparent approval in the *Valley Drug* case, 344 F.3d at 1309.

⁵⁶ H.R. Rep. No. 98-857, *supra* note 1, at 28, 1984 U.S.C.C.A.N. at 2661. *See also Andrx Pharms. v. Biovail Corp.*, 256 F.3d at 802 (Congress “interested in increasing the availability of generic drugs” but also interested in protecting “the patent rights of the pioneer applicant”).

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the “traditional” regime. The shift in the relative bargaining power of the litigating parties may mean – assuming other factors are held constant – that pioneers will have to accept earlier entry dates in settlement than they would otherwise have had to do. The baseline for a competitively benign settlement may have shifted. Whether this is good or bad is a judgment for Congress to make. Furthermore, we do not have evidence before us to justify any conclusion that payments by pioneers to generics are a “natural by-product of the Hatch-Waxman process”⁵⁷ or that Congress intended to immunize payments of this kind.

We therefore believe that the possible existence of a so-called “reverse payment” raises a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry.⁵⁸ All of the pioneer/generic patent settlements that we have thus far challenged included a payment of this kind.⁵⁹ In fact, the evidence indicates that antitrust counsel for the pioneer, Schering, was also concerned about the legal implication of a possible payment to generic challengers. *See, e.g.*, CX 1494 at 71 (Driscoll IH); CX 1509 at 35 (Hoffman IH); Rule, Tr. 2583-84. However, for the reasons discussed above and in Part III below, we are not now prepared to say that all such payments should be viewed as *per se* illegal or “inherently suspect.” We believe that this particular case warrants a more extensive analysis of competitive effects, without foreclosing the possibility that a more truncated process would be appropriate in some future case.

⁵⁷ *See also* discussion of ancillarity in Part III, below.

⁵⁸ *See supra* note 51.

⁵⁹ *See cases cited supra* note 3.

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C. The Need to Address the Merits of the Underlying Patent Dispute

The Respondents argued, and the Administrative Law Judge held, that proof of anticompetitive effects requires proof on the merits of the underlying patent claims. ID at 4, 103-04. We deal with the argument in this segment of the opinion because it is not really a “defense” but rather a fundamental attack on the sufficiency of Complaint Counsel’s affirmative case. It is also an argument that, if valid, would have an impact not only on this particular case but also on other antitrust cases before the Commission and the courts that involve the legality of patent settlements.

Respondents’ argument and the conclusions of the Initial Decision on this issue have a superficial appeal. The argument proceeds as follows: Complaint Counsel have the burden of proving that the agreement delayed generic entry but failed to prove that earlier entry would have been possible in the first place, in light of the patent blockade. By statute, Schering’s patent is presumed to be valid (35 U.S.C. § 282) and Complaint Counsel failed to prove it was not. Since the holder of a valid patent has the right to exclude infringing products entirely for the life of the patent, the settlement agreement was procompetitive because it permitted generic entry some five years *before* the expiration of Schering’s patent.

We reject this argument for a number of independent reasons. First, Schering’s presumptively valid patent did not necessarily confer a right to exclude generic entry in the circumstances of this case. Second, there is a recognized distinction between the standard for proving that an agreement is likely to cause competitive harm and the standard for proving damages after the fact. Third, we believe that an inquiry into the merits of the patent case would not be conclusive in most of our antitrust cases anyway. Fourth, we are also concerned that a mandated inquiry into these issues, as part of an antitrust review, would ultimately

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have a chilling effect on the efficient settlement of patent litigation.

We observe, first, that the Initial Decision suffers from a fundamental logical flaw. The fact that Schering may have held a presumptively valid formulation patent on K-Dur 20 does not mean that it had a presumptive right to preclude the entry of Upsher's generic product. One issue in the patent case – perhaps the most important one – was not whether Schering's patent was valid but rather whether Upsher's product infringed the patent. IDF 129, 130. On this issue, Schering had the burden of proof.⁶⁰ We cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

Second, we are not aware of any federal court opinions that hold it is necessary for complaint counsel in a government proceeding to offer proof on the underlying merits of the patent dispute, in order to establish their affirmative case. The point was discussed in the recent *Tamoxifen Citrate Antitrust Litigation*, 262 F. Supp. 2d 17, where the court dismissed an antitrust challenge to an agreement that settled a patent dispute between a pioneer and a generic manufacturer, with terms that included a payment from the pioneer to the generic. In return, the generic had agreed not to market its own version of the Tamoxifen drug prior to the expiration of the patent, but instead took a license to sell product manufactured by the pioneer.

⁶⁰ See, e.g., *Carroll Touch, Inc. v. Electro Mechanical Systems, Inc.*, 15

F.3d 1573, 1578 (Fed. Cir. 1993). The Initial Decision assumed that Upsher had the burden of proving either patent invalidity or “that its product . . . did not infringe Schering's patent.” ID at 103 (emphasis added). This is not correct.

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In that case, however, the validity of the pioneer's patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, the pioneer's patent was successfully defended in litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* court had good reason to believe that the settlement did not ultimately cause consumer harm. In the present case, on the other hand, we do not attempt to assess damages but rather look at the agreement as of the time it was made to determine whether it was "unreasonable," *i.e.*, whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement.

A contemporaneous opinion from the same district court in the *Ciprofloxacin Hydrochloride Antitrust Litigation*, discussed at length above in connection with another issue, expressly rejected the argument that an antitrust attack on a Hatch-Waxman settlement requires proof on the merits of the underlying patent case. Notwithstanding the fact that the underlying patent dispute between the pioneer and the generic manufacturers involved patent validity, not infringement, and the fact that subsequent to the settlement the pioneer had successfully defended the validity of its patent in litigation with others, the court found that the existence of an antitrust violation does not depend on the merits of the patent case.⁶¹ At the time of the settlement, the parties did not know who would ultimately prevail, and the court noted that

. . . the challenged agreements allowed [the generic] to accept cash in exchange for an agreement to halt the process by which a court would make . . . a determination [of patent validity and infringement] – a process encouraged by the Hatch-Waxman Amendments and beneficial to consumers.

⁶¹ The *Ciprofloxacin* court appropriately cautions that the standard for proof of damages may be different. *Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 199.

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Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 204. The court therefore rejected the pioneer's argument that it was patent law, not the agreement, that precluded generic entry. Although the court also rejected plaintiffs' claim of *per se* illegality, it indicated that the matter could proceed under a rule-of-reason inquiry. *Id.* at 210-11.

We agree with the reasoning of the *Ciprofloxacin Hydrochloride* court on this issue. The merits of the patent litigation may be crucial in an action for damages but we are here concerned only with legal liability, and we focus on the state of the world as it was perceived by the parties at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out.⁶²

A similar view was expressed by the court in *Valley Drug*, cited earlier for its rejection of a *per se* standard. In *Valley Drug*, the sole issue in the underlying patent litigation was patent validity and, after an interim settlement, the patent in issue had been declared invalid in a separate proceeding. The court said:

We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness

⁶² The uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced. If, for example, an incumbent entered into an agreement with a would-be market entrant in which the latter agreed to delay or forgo introduction of a new product, it would be no defense to argue that the new product *might* not have succeeded in any event.

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of agreements under the antitrust laws are [sic] to be judged at the time the agreements are entered into.

Valley Drug, 344 F.3d at 1306 (citations omitted).

The court went on to say:

Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

Id. at 1308.

The *Valley Drug* opinion, of course, was concerned only with the narrow issue of whether a subsequent finding of patent invalidity necessarily made it *per se* illegal for the pioneer patent holder to pay a generic challenger for entry delay – even though the litigation outcome was uncertain at the time. We believe, however, that the underlying logic of the opinion has a broader application. We question the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case. This is the third independent basis for our conclusions.

In an extreme case, the inquiry might be helpful. If it appeared that the patent claim was objectively a sham, any agreement to delay generic entry might be viewed as anticompetitive, regardless of the other terms. Conversely, if it appeared that the generic's Paragraph IV certification was objectively a sham, it might be difficult to claim that an agreed-on entry date before the patent termination involved an unacceptable delay.⁶³ The problem is that

⁶³ A case like *Tamoxifen* (discussed above), where patent validity was the only issue and the patent had been repeatedly upheld, might also be included in this category.

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the bulk of the cases will lie in between.⁶⁴

An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement. We observe this natural phenomenon in the present case. Upsher's ANDA filing had certified that Schering's K-Dur 20 patent was either invalid or not infringed by Upsher's product. Later on, Upsher's counsel in the patent litigation represented to the court that the only impediment to its immediate entry was the automatic Hatch-Waxman stay. CX 1705 at USL PLD 004242 (*in camera*); Kerr, Tr. 6744-45. After the settlement, Upsher's views dramatically changed. At trial, Paul Kralovec, Upsher's CFO, testified that, because of the financial risk arising from damages for infringement, a decision was made that Upsher would not market Klor Con M20 until the outcome of the litigation was known. Kralovec, Tr. 5037-38.

⁶⁴ Take the simplest possible case as an example. Suppose it appears *post* settlement that each party reasonably had a 50/50 expectation of victory. Does this mean that a 50/50 split of the remaining patent term would be the only reasonable settlement? This assumption would not necessarily be true for reasons that the Respondents themselves have addressed in great detail. *See* Part III, below. The parties may have very different financial resources, profit expectations and risk preferences, with consequently differing views on the costs and benefits of further litigation. These differing views would have an effect on the outcome of settlement negotiations, and litigation odds cannot be converted directly into the legally acceptable period of delayed entry.

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The fact that the generic's counsel has switched sides does not destroy all potential for an adversary proceeding. It is theoretically possible for Complaint Counsel to step in for the generic's newly complaisant counsel and champion the generic's abandoned claims, or the Commission could weigh conflicting opinions of opposing experts. If it were logically necessary to decide the issue of patent validity in order to decide whether the agreements in issue here were reasonable, we would do so – regardless of the difficulties. However, for the reasons discussed, it is not necessary.

Finally, we have considered the serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight. Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack. This test may not be perfect, but at least it is easy to apply at the time of settlement, when the outcome of the patent case is uncertain. If a subsequent examination of the merits were decisive, the parties could not be sure. If the generic's position were later determined to be invalid, then any entry short of patent expiration would likely be immune from attack. If, however, the pioneer's position were found to be invalid, *any* delay would be suspect. Respondents' argument might serve their interests in this particular case, but it could have a chilling effect on patent settlements down the road, and thus make it harder for parties to enjoy the advantages of certainty.⁶⁵

For these various reasons, we believe that it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements. To

⁶⁵ See *Valley Drug*, 344 F.3d at 1306-07; Willig, Tr. 7148, 7173-75.

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the extent that the opinion of the Administrative Law Judge is predicated on any such requirement, it is reversed.⁶⁶

III. The Ancillarity Defense

Both Schering (implicitly) and Upsher (expressly) plead that even if the \$60 million payment to Upsher were deemed to have been traded for delay, it was justified as ancillary to a legitimate, pro-consumer agreement, namely, the settlement of a patent dispute. Schering Answer at ¶¶ 1-3; Upsher Answer at Defenses ¶ 10. They offered evidence – principally through their expert witness, Professor Robert Willig – that Professor Bresnahan’s paradigm was overly simplistic. Professor Willig testified that the payment of net consideration from the pioneer to the generic must be considered in the overall context of procompetitive patent settlements that it may facilitate. We, therefore, will examine these claims under familiar principles applicable to ancillarity defenses.

The Antitrust Guidelines for Collaborations Among Competitors⁶⁷ set out the analytic framework that we will apply in this situation.⁶⁸ These Guidelines (Sec. 3.2) provide that even a

⁶⁶ For reasons also discussed above, however, this conclusion about what the Commission needs to do in this case does not necessarily have any bearing on what a private plaintiff may need to do in order to prove damages.

⁶⁷ See Antitrust Guidelines for Collaborations Among Competitors, *supra* note 27.

⁶⁸ The Guidelines are intended to reflect current law, not to catalyze changes. See Susan S. DeSanti, Guideposts in the Analysis: The Federal Trade Commission and U.S. Department of Justice, Antitrust Division Competitor Collaboration Guidelines, Address Before the Houston Bar Association (Dec. 7, 1999), *available at*

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provision that would be *per se* illegal standing alone can qualify for rule-of-reason treatment in certain circumstances. Therefore, even if we assume that Schering overtly agreed to pay Upsher a substantial sum for delayed entry, it is necessary to examine that payment in the context of an overriding purpose to settle the patent case.

Under the Guidelines, respondents who assert an ancillarity claim have the burden of showing three things (Sec. 3.2):

- (i) that there is an “efficiency-enhancing integration of economic activity . . .”;
- (ii) that the arguably ancillary agreement is “reasonably related to the integration . . .”; and
- (iii) that it is also “reasonably necessary to achieve . . . [the] pro-competitive benefits” of the overall arrangement.

Id.

We accept Willig’s testimony that there are likely to be efficiencies associated with the settlement of patent disputes between pioneer and generic manufacturers. *See, e.g.,* Willig, Tr. 7134, *et seq.* A settlement can save public and private resources that would otherwise be consumed by litigation, and it can provide certainty that will encourage business investment. We also recognize, as he testified, that there may be hypothetical situations where a procompetitive settlement could require payment of some money to the generic challenger. This means that we are unwilling to say reverse payments included in a settlement agreement are always illegal.⁶⁹ On the other hand, the mere

<<http://www.ftc.gov/speeches/other/antitrustguidelines.htm>>.

⁶⁹ *See Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (Section XII(B)(1)(b) of Decision and Order does not prohibit respondent from settling patent infringement litigation with a payment from the pioneer to generic manufacturer if payment is

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articulation of hypothetical circumstances where reverse payments could ultimately facilitate an efficiency-enhancing settlement does not mean that a particular settlement is legal. If Complaint Counsel have made out a *prima facie* case that the agreement was anticompetitive, the burden is on these Respondents to demonstrate that these hypothetical circumstances describe the realities of the present case. They have not done so.

Willig hypothesized, for example, that a “cash starved” generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer. Willig, Tr. 7180, 7188, 7258. It is possible that this trade might ultimately yield competitive benefits, but a respondent that relies on this argument also must show that the generic, in fact, was cash starved; explain why the pioneer was the best source for the necessary funds; and demonstrate that the up-front support actually resulted in an entry date earlier than would be expected without it. We have no evidence that would establish these conclusions. To the contrary, Upsher expressly waived any intention to rely on financial need as a defense in this action.⁷⁰ It is true that Schering may have believed Upsher needed the money because Upsher’s lead negotiator said so repeatedly in the course of the settlement discussions, but it is also true that Schering did

less than \$2 million or expected litigation costs), *available at* <http://www.ftc.gov/os/2003/03/bristolmyersdo.pdf>. *See also* Final Order in this case, at Paragraph II.

⁷⁰ CX 1693 (Letter from Rajeev K. Malik to Yaa A. Apori Providing Upsher’s Responses to Specifications 4, 5 and 8 of Complaint Counsel’s First Request for Production of Documents (Aug. 28, 2001) (“The agreement is Upsher-Smith does not have to produce documents in response to Specification 8 [requesting financial information]. In exchange, Upsher-Smith commits to Complaint Counsel that it will not raise a defense that uses Upsher-Smith’s financial condition as a justification for entering into the licensing agreement with Schering-Plough.”)).

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not rely on any such belief to establish the legality of the \$60 million payment. *See* discussion in Part IV.B., below. As a matter of fact, Upsher was not cash-constrained; the company passed on to its shareholders an amount equal to or in excess of the sums received from Schering. *Kralovec*, Tr. 5067.

There are other possibilities. Risks and costs associated with litigation are avoided by settlement. If the generic challenger is more optimistic about the litigation outcome than the pioneer, a pioneer may be willing to pay some money to bridge the gap in the expectations. *Willig*, Tr. 7195; *Addanki*, Tr. 5761, 5776, 5793. It is also possible that there are widely differing risk preferences. A judgment-proof generic manufacturer may be willing to hold out for “unreasonable” settlement terms because its downside risks of damage exposure are small.⁷¹ *Addanki*, Tr. 5793-94.

We recognize that additional legitimate justifications can also exist, and this is another reason why we do not apply a truncated analysis in this particular case. However, once Complaint Counsel have made out a *prima facie* case of actual anticompetitive effects, Respondents must do more than suggest hypothetical benefits.⁷²

In this case, the sheer magnitude of the payment from the pioneer to the generic is a particular source of concern. Even if we assume *arguendo* that there had been enough evidence to show that the hypothetical speculations of Respondents’ experts actually applied to the facts of this case, the evidence could not justify a

⁷¹ For the reasons discussed above, it may be difficult to identify a particular settlement demand as objectively “unreasonable.”

⁷² *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,459, slip op. at 30-31 (“a justification must plausibly create or improve competition.”).

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payment of any amount close to the \$60 million involved here. We deal with an ancillarity defense predicated on the notion that there is a strong public policy in favor of litigation settlements – even if the settlements may involve agreements that might be illegal standing alone. But, these public policy considerations are just one weight on the scale; they do not mean that all settlements are presumptively efficient regardless of the cost.⁷³

We conclude that Respondents' ancillarity defense has failed. A payment in the order of \$60 million could not be defended under these facts as a reasonably necessary element of a settlement that is procompetitive overall. The parties did not show that the hypothetical situations where such a payment might be justified actually were present in this case. The ancillarity claim is rather based on after-the-fact rationalization. During the course of the settlement negotiations, recounted in detail below, Upsher's representatives seemed to be entirely oblivious to the potential legal consequences of their demand that money be paid for delayed entry. Schering's representatives were sensitive to these concerns but believed that the solution was to find some side deal that would justify the payment by itself. We now examine Schering's "solution."

IV. Consideration for the Upsher Licenses Granted to Schering

Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the \$60 million payment from Schering to Upsher. App. Br. at 3. We interpret this to mean that Complaint Counsel's test is whether \$60 million was a fair price for the licenses from Schering's standpoint, regardless of what

⁷³ Herbert J. Hovenkamp, *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003) (payment by a pioneer to a generic in excess of litigation costs is not an economically efficient solution to the dispute and likely biases the negotiated entry date toward later entry).

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they were worth to Upsher.⁷⁴ We express no view as to whether a concession of this kind is necessarily appropriate. Since, however, it is the basis on which this case has been litigated, we will proceed on the same premise.

This is also an issue on which Complaint Counsel have conceded that they bear the ultimate burden of proof. O.A. at 30 (“we have the burden to prove the payment was for delay”). This is not to say that Complaint Counsel bear the burden of proving the actual value of the licenses. What we understand they have undertaken to prove is (i) that there is a nexus between the payment by Schering and Upsher’s agreement to delay its competitive entry, and (ii) that the preponderance of the evidence shows that this payment exceeded, by a substantial amount, Schering’s reasonable expectation of the value of the Upsher licenses. App. Br. at 22-24 (“ . . . the Commission need not conclude that the license for [Niacor-SR] was a ‘sham’ or that it lacked any value to Schering.”). This is the standard that we will apply.

The Initial Decision contains extensive findings on this issue. However, for reasons that will become clear, many specific findings and the ultimate factual conclusions in the Initial Decision are flawed. Accordingly, we review the entire factual record *de novo*, and, where appropriate, substitute our own findings and conclusions for those in the Initial Decision. We will focus on (A) the plain language of the agreement; (B) the background and history of the settlement negotiations; (C) the extent of Schering’s internal investigation of the value of the Upsher licenses, considered in light of the information it had already obtained in the course of recently terminated negotiations

⁷⁴ Complaint Counsel’s witness Bresnahan testified that “if Schering-Plough had made a stand-alone determination that it was getting as much in return from these products as it was paying, then I would infer that they were not paying for delay.” Bresnahan, Tr. 964-65.

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with another company for a similar product; and (D) the inferences that may appropriately be drawn from the subsequent conduct of the parties and after-the-fact opinions about the value of the licenses.

This part of the opinion is necessarily detailed. There is no single event, no single communication, that determines the outcome. Our conclusion that Complaint Counsel have sustained their burden on the critical valuation issue rather depends on the cumulative impact of the extensive record evidence in this case.

A. The Language of the Settlement Agreement

The “Detailed Agreement Terms” between Upsher and Schering provide, in pertinent part:

3. Upsher-Smith agrees that it will not market in the United States its KLOR CON[®] M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001.

* * *

11. In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, SP licensee [a Schering affiliate] shall make the following payments to Upsher-Smith: . . .

CX 348 at USL03186, USL03188.

The contract then sets out a schedule for payment of \$60 million, keyed to specific time periods following approval by the Schering Board. The payments are not dependent on milestones in the development of products licensed from Upsher to Schering,

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such as FDA filings or approvals.⁷⁵ The only ongoing affirmative obligation of Upsher, apart from its commitment not to enter before September 1, 2001, is a promise that it will not assist ESI or any other party that challenges Schering's patent. CX 348, Par. 6.

We do not believe this contractual language is conclusive by itself. What it does show is that at least part of the consideration for the \$60 million payment was Upsher's commitment to delay entry, something that Schering's in-house counsel has readily conceded. Hoffman, Tr. 3565-67. Even more significant, payment was not conditioned on Upsher's cooperation with Schering in the development of the licensed product. The omission may well have been deliberate because, after the Agreement became effective, Upsher did practically nothing to cooperate and Schering did not seem to care. *See* discussion in Part IV.D., below.

B. Background and History of the Negotiations

The Initial Decision relies on direct trial testimony of several individuals for a description of the negotiations between the parties that resulted in the June 17, 1997 agreement. IDF 131-55. It does not cite contradictory cross-examination testimony or investigational hearing testimony of several of these individuals, nor does it explain why this testimony was given no weight – even when the contradictory testimony is corroborated by documentary evidence.⁷⁶ There are particularly significant discrepancies in the

⁷⁵ Additional contingent milestone payments that could total \$10 million were negotiated for the launch of Niacor-SR in nine other countries.

⁷⁶ Upsher continues to press its objection to the use of the testimony of Schering executives during the investigational hearings and to rely on a pretrial ruling that this testimony is not admissible against Upsher. Upsher Ans. Br. at 22 n.2, citing Tr.

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testimony of Ian Troup, Upsher's President and Chief Operating Officer, and John Hoffman, Schering's Associate General Counsel. Accordingly, as detailed below, the Commission discounts inconsistent trial testimony of these two individuals.

The Initial Decision also does not cite important deposition testimony of a primary negotiator for Schering in the early meetings between the two companies (Martin Driscoll, Vice President of Sales and Marketing for Key Pharmaceuticals), even when it is consistent with his investigational hearing testimony. *See, e.g.*, CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.) (views of the parties about payments to Upsher and entry into the market). The Initial Decision relies on direct testimony of some witnesses for facts about which they had no firsthand knowledge and for which other individuals with differing testimony would have been more reliable sources. For example, IDF 136 relies on Hoffman, who did not attend either the May 28 or the June 3 meeting, for a description of the events at these meetings. IDF 145 relies on Troup's recollection of a discussion with Schering personnel of certain clinical data about Niacor-SR, but these Schering employees had no knowledge of these issues.

297-98. We do not agree with this ruling. *See Gibson v. FTC*, 682 F.2d 554, 568 (5th Cir. 1982) (“[T]he Commission Rules of Practice [§ 3.43(b)] permit the introduction of hearsay evidence, provided that it meets the standards of materiality, reliability and relevance.”). The hearing transcripts in issue are verbatim statements of the witnesses, and Upsher does not explain why they are unreliable. In any event, however, we rely on these transcripts merely to corroborate evidence from other sources. The testimony specifically affected by this ruling is contained in CX 1483, 1494, 1508, 1510, 1515 and 1531. There is independent support for any factual findings in this Opinion that may also refer to these exhibits.

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The Initial Decision also relies on self-serving statements of the parties without weighing contradictory, and more reliable, evidence.⁷⁷ For example, IDF 145 indicates that the parties discussed “the market potential for Niacor-SR” and that they also “discussed niacin combination therapy, the advantages of Niacor-SR versus immediate-release niacin, the flushing side effects and Niacor-SR’s effects on Lp(a).” Troup’s statements, on which the finding is based, are contradicted by Schering’s lead negotiator, Raman Kapur, who testified that there was no scientific discussion on the merits of Niacor-SR. CX 1511 at 71-72 (Kapur Dep.) (indicating no discussion of Niacor-SR’s clinical results). Indeed, the Initial Decision fails to note that the discussions did not include Schering personnel with knowledge about niacin-related products. None of the Schering personnel involved in the recently terminated negotiations with Kos Pharmaceuticals were involved in the Upsher negotiations; Driscoll, the only person with firsthand knowledge of the Kos product, had dropped out of the negotiations with Upsher at this point.

In light of these shortcomings, the Commission has undertaken a *de novo* review of the record and substitutes the following findings for IDF 131-55. It is necessary to cite the testimony of many individuals. Throughout this opinion, we have identified the affiliations of all witnesses when they are first mentioned, and these identifications are also set out in an Appendix.

⁷⁷ To avoid any possible misunderstanding, we emphasize that we do not automatically discount testimony simply because it is self-serving. Most witnesses with knowledge of the facts have some stake in the outcome of a proceeding like this one – intellectual or emotional, if not financial. However, when the trial testimony of a strongly self-interested witness conflicts with the same witness’s earlier testimony in a more unguarded moment, with contemporaneous documents, or with statements of less interested witnesses, it is necessary to take account of these alternative versions of the facts.

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1. Findings of Fact on the Negotiations Between Schering and Upsher

In April or May 1997, Troup first approached Schering about a possible settlement of the patent litigation. Troup, Tr. 5397, 5407-09. The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation.

The initial settlement meeting took place between Driscoll and Troup at Schering's office in Kenilworth, New Jersey on May 21, 1997. Troup, Tr. 5409-10. This was the first of five face-to-face meetings between Schering and Upsher. Troup stated that his settlement objective was to obtain the earliest possible launch date for Klor Con M20 without incurring the damages that could arise from patent infringement. Troup, Tr. 5411-12. Driscoll recalled that Troup said in the initial meeting that the only way Upsher would settle the patent litigation was for payment of \$60 million to \$70 million and the ability to market within the year (an entry date). CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.). Driscoll recalled that the \$60 million to \$70 million was the estimated adverse impact on Schering of Upsher's entry and that Troup wanted a percentage of that impact. CX 1494 at 67 (Driscoll IH). It was value that Upsher had to have.⁷⁸ CX 1495 at 58 (Driscoll Dep.). Driscoll stated forcefully that Schering would not pay. CX 1494 at 66 (Driscoll IH); CX 1495 at 58 (Driscoll Dep.).

⁷⁸ Upsher's insistence on a payment persisted throughout the negotiations. *See* CX 338 (summary forwarded to the Schering Board when it approved the settlement agreement in issue, stating, "In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from the sales of Klor Con had they been successful in their suit.").

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At this meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. Troup, Tr. 5412. Troup stated that Upsher wanted to be on the market at an earlier date and that it would have problems with cash flow if its entry were delayed until 2005. Troup, Tr. 5413. There is, however, no record support for Troup's claim of financial need (Kralovec, Tr. 5067), and Upsher disclaimed any intention to rely on it, in order to avoid disclosure of financial information during the discovery stage of this proceeding.⁷⁹

The parties met again at Upsher's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Driscoll and Raman Kapur, President of Schering's Warrick subsidiary that markets generic drug products, attended these meetings on behalf of Schering. Troup and consultant Andrew Hirschberg attended on behalf of Upsher. Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions Nos. 7-9, 11-12; Upsher Second Admissions Nos. 9-10, 13-14, 22. At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher's generic products. Troup, Tr. 5420.

At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture where Schering would invest \$14 million into Upsher's research and development efforts. CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34; USX 477 (Troup's contemporaneous notes of the June 3, 1997 meeting). They also discussed the possibility that Schering might license one or more Upsher products. The discussion during the May 28 meeting focused on settlement of the K-Dur litigation and there was a brief discussion of licensing cholestyramine (one of the generic products Upsher ultimately licensed to Schering as Prevalite) at the end of the

⁷⁹ See Part III, above.

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meeting. CX 1511 at 14 (Kapur Dep.). The parties did not discuss Niacor-SR until the June 3 meeting and Upsher did not provide written material to Schering personnel at this meeting. CX 1530 at 70 (Troup Dep.); CX 1511 at 14 (Kapur Dep.); CX 1495 at 62 (Driscoll Dep.); CX 1511 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34.

Driscoll was aware of the market opportunity for Niacor-SR because he had been involved in evaluating the market for other, nearly identical projects. CX 1495 at 70-71, 73 (Driscoll Dep.). Troup was willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, because Upsher had no international presence. Troup, Tr. 5432.

During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. CX 1511 at 18-19 (Kapur Dep.). Troup stressed Upsher's need to replace the revenue it would lose if it did not have a generic K-Dur 20 product on the market. CX 1511 at 18-19 (Kapur Dep.).

During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher's entry with its generic version of K-Dur 20. CX 1511 at 22-23 (Kapur Dep.). Troup preferred an earlier date. CX 1511 at 23-24 (Kapur Dep.); CX 1529 at 100 (Troup IH); Troup, Tr. 5505-5507. The record evidence is unclear on who offered the September 1, 2001 date. Driscoll does not indicate, in either his investigation hearing or deposition testimony, that he offered a date earlier than 2005. Kapur recalled, however, that Driscoll told Upsher the earliest date he could offer for Upsher's entry was September 2001. CX 1511 at 23 (Kapur Dep.).

Regardless of who offered the September 1, 2001 entry date, the weight of the evidence indicates that the parties had not agreed upon the entry date of September 1, 2001 at the end of the June 3 meeting. Troup testified in his investigational hearing that the date had not been agreed to and that he would get back to

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Schering on the entry date after the June 3, 1997 meeting. CX 1529 at 100 (Troup IH). In his later deposition and trial testimony he stated that the date was settled by the end of the June 3, 1997 meeting, although he stated that he did not remember exact dates. CX 1530 at 82 (Troup Dep.). Hoffman, who attended his first meeting with Upsher personnel on June 12, testified both in his investigational hearing and on cross-examination at trial that the entry date was not even settled upon until after the next meeting on June 12, 1997. Hoffman, Tr. 3563; CX 1509 at 42 (Hoffman IH). Although Hoffman's direct trial testimony and deposition testimony are to the contrary, we find that his testimony on cross and the earlier investigational hearing is more credible. Therefore, we find that the negotiations on an entry date cannot be viewed as concluded by June 3, 1997, nor do we find that it was a matter separate and apart from other terms and provisions in the final agreement dated June 17, 1997.

Driscoll recalled that he ended his participation in the negotiations with Upsher after the June 3 meeting, even though he was head of the affiliate responsible for K-Dur. He stated that Troup wanted money to settle and Schering would not pay, so he decided to let the lawyers work it out. CX 1494 at 71-72 (Driscoll IH).

Before the parties' next face-to-face negotiation session, Hoffman spoke to Nick Cannella, Upsher's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. Cannella, Tr. 3824-25. Upsher representatives Troup, Cannella and Hirschberg, and Schering representatives Kapur and Hoffman, met in Kenilworth, New Jersey, on June 12, 1997. Troup, Tr. 5436-38; Hoffman, Tr. 3539, 3541-42. It is unclear from the evidence whether Jeffrey Wasserstein, Schering's Vice President of Business Development, attended this meeting. CX 1532 at 25-26 (Wasserstein Dep.); CX 1510 at 54 (Kapur IH) (Kapur indicating that only he and Hoffman attended the June 12, 1997 meeting).

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The purpose of the June 12, 1997 meeting was to continue discussion of the potential for settlement of the lawsuit and the licensing of certain Upsher products. CX 1509 at 34 (Hoffman IH). The parties discussed a settlement proposal under which Schering would give Upsher a royalty-free license at some time before expiration of the patent, and the timing of entry would be based on the parties' potential for success or failure in litigation. CX 1509 at 34 (Hoffman IH). Hoffman indicated that Schering would not pay to settle the litigation. CX 1509 at 35 (Hoffman IH). Hoffman testified that Upsher's consultant (Hirschberg) provided an estimate of how much Schering stood to lose if Schering lost the suit. CX 1509 at 35 (Hoffman IH); Hoffman, Tr. 3544. There was agreement at the end of this meeting that the parties would settle the litigation, through a royalty-free license at some time prior to patent expiration, but no particular date had been picked. CX 1509 at 42 (Hoffman IH). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher's generic version of K-Dur. Troup, Tr. 5439; CX 1529 at 101-02 (Troup IH).⁸⁰ Troup stated at the June 12 meeting that Upsher still had "cash needs" because all of the company's cash was tied up in two products in development – Upsher's generic version of K-Dur and its similar sustained-release niacin product, Niacor-SR. Hoffman, Tr. 3543.

Before the June 12, 1997 meeting, Upsher required Schering to sign a confidentiality agreement regarding Upsher's Niacor-SR product information. CX 1041. Troup brought to the meeting a confidential printed presentation about Upsher's Niacor-SR product. Troup, Tr. 5436-37; CX 1042. This presentation was similar to the presentations Upsher provided to Searle and the European companies interested in licensing Niacor-SR. USX

⁸⁰ Upsher's own witness, Troup, apparently did not regard the entry date as settled, even as late as June 12.

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538; CX 1023.⁸¹ Troup also provided Schering with two draft protocols for conducting post-market studies of Niacor-SR. CX 714; CX 1043. Neither Kapur nor Hoffman had participated in the earlier negotiations with Kos on a niacin-related product. *See* Part IV.C.1, below.

Troup confirmed that Upsher's offer of a Niacor-SR license extended only to non-NAFTA territories. Hoffman, Tr. 3545; Troup, Tr. 5440-41. Schering was disappointed that Upsher would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested

⁸¹ Through a consultant, Upsher contacted European companies to solicit interest in Niacor-SR. The first wave of contacts covered 32 companies. All but one of the companies in the first wave declined the opportunity or failed to respond. CX 888 (consultant's report summarizing responses received). The second wave of contacts covered additional smaller European companies. Four companies expressed interest in meeting with Upsher. Meetings with these four companies took place between May 28, 1997 and June 5, 1997. The meeting summaries assessed three of the potential licensees' interest as "moderate" or "low." CX 868 (Esteve meeting summary); CX 880 (Lacer meeting summary); CX 883 (Servier meeting summary). Only one partner, Pierre Fabre, was assessed as "moderately to highly interested," "if we can negotiate an acceptable deal." CX 881 at USL11826. That company expressed concerns in its meeting with Upsher about the safety of Niacor-SR, and questioned what kinds of payments might be involved because it had met with start-up companies that were asking "unreasonable payments of at least \$50 million." CX 881 at USL11825-26. These tepid results were reported back to Troup. USX 1532 at 145 (O'Neill IH); Troup, Tr. 5570; USX 596-98; CX 880.

The other potential partner, Searle, "had no interest in further pursuing the product" because of questions about Niacor-SR's safety, in particular its toxicity profile. Egan, Tr. 7886.

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in the opportunity to market the product internationally. Troup, Tr. 5443-44. Kapur also expressed his continued interest in Upsher's cholestyramine and Pentoxifylline products. Hoffman, Tr. 3545.

Troup made a brief presentation on Niacor-SR and brought written materials. Hoffman, Tr. 3544. Troup had not attended Upsher's presentations to other potential European partners, and none of the Upsher employees who had given the Niacor-SR presentation to other potential partners – including Halvorsen, Freese, and O'Neill – were present at the meeting with Schering. Troup, Tr. 5436-38; Hoffman, Tr. 3541-42. The parties discussed the market potential for Niacor-SR. Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868. Troup referred to Kos Pharmaceuticals' Niaspan product, its market capitalization and sales potential, to show that Upsher's Niacor-SR niacin product had tremendous potential. Troup, Tr. 5441-43; Cannella, Tr. 3829-30.

The June 12, 1997 meeting included a preliminary discussion of the price for the Niacor-SR product. Troup asked for \$70-80 million in his first offer to Schering. Troup, Tr. 5449; Hoffman, Tr. 3545; CX 1511 at 44-45 (Kapur Dep.); Cannella, Tr. 3829. Troup did not base his asking price on Upsher's own estimates of the potential market for Niacor-SR. Upsher had not yet forecasted sales for the European/ex-U.S. markets, but its sales projections for the U.S. market were uniformly low.⁸² A series of Upsher internal projections in 1996 and 1997 (before the Agreement) predicted sales in the \$10 million range or below in the first year; the highest estimate was for \$20 million in sales in the second

⁸² Troup testified that he considered the ex-U.S. market to be about the same size as the U.S. market. Troup, Tr. 5528. Kos, Searle, and Schering believed that the U.S. market potential was larger than the ex-U.S. market. CX 1470 at SP 002748 (Schering's Contact Report of April 9, 1997 describing meeting with Kos); Egan, Tr. 7915-16.

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year of one projection. CX 234 at USL12785, USL12797; CX 322 at 05287; CX 778 at 15531. As of September 1997, Upsher projected U.S. sales for Niacor-SR of only \$9.6 million and \$11.5 million in its first and second years on the market. CX 1094 at 11935; *see also* CX 930 at 13191 (July 1997 projection of \$7-8 million for Niacor-SR sales in 2003). These projections were based on Upsher's perception – based on actual sales data, not estimates – that the sustained-release niacin market had *decreased* in both dollar and volume terms. CX 929 at USL 13138 (March 1997).

Schering told Upsher it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher about its interest in pursuing a deal for Niacor-SR. Hoffman, Tr. 3545-46; Cannella, Tr. 3832. The parties also discussed potential licenses for other Upsher products, including Prevalite and Pentoxifylline (Troup, Tr. 5445-46; Hoffman, Tr. 3545), but these other products were not part of the deal at this point. Hoffman, Tr. 3545. The parties had not reached agreement on the settlement or licensing at the conclusion of this meeting. Hoffman, Tr. 3545.

Shortly before or after the June 12, 1997 meeting with Upsher in Kenilworth, Kapur and Driscoll briefed Schering's president of pharmaceuticals worldwide, Raul Cesan, on the Upsher negotiations. CX 1510 at 66-67 (Kapur IH); CX 1511 at 29-30 (Kapur Dep.). Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. CX 1511 at 30 (Kapur Dep.). Cesan asked Kapur to contact Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. CX 1511 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.).

In accordance with Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing

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opportunity for Upsher's sustained-release niacin product that would cost Schering approximately \$60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth \$60 million to Schering. Lauda, Tr. 4342-43. This is the same sum that Troup had demanded to settle the patent litigation.

Lauda asked James Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform a commercial assessment of Upsher's Niacor-SR product. Lauda, Tr. 4344. Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert might have. Lauda, Tr. 4404. Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware that the Niacor-SR opportunity had any connection to a patent suit. Audibert, Tr. 4113.

The final meeting between Schering and Upsher took place on June 16, 1997, in Upsher's office in Plymouth, Minnesota. Troup, Tr. 5452; Hoffman, Tr. 3550. Kapur, Hoffman, Wasserstein, and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher. Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834. The discussion again centered on the patent settlement and Upsher's claim that it needed cash flow to run its business. CX 1532 at 30 (Wasserstein Dep.). This testimony is confirmed by Hoffman, who recalled that Troup linked Schering's proposal for a license to take effect in the future with Upsher's cash needs in the interim. CX 1509 at 76 (Hoffman IH).

Discussion then turned to the valuation of the package of Upsher products, including Niacor-SR and Pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. Troup, Tr. 5453. Over the course of the meeting, Upsher offered to license its wax matrix 8 and 10 mEq products and Klor Con M20 to Schering for the ex-NAFTA countries. Troup, Tr. 5453. Troup

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still wanted \$80 million. Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835. Schering made a counter-offer of \$60 million, which Upsher accepted. Cannella, Tr. 3835; Troup, Tr. 5458.

The parties discussed, either at the June 16 meeting or shortly thereafter, that the \$60 million would be paid in installments. Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511 at 74-75 (Kapur Dep.). To bridge the gap between Upsher's asking price and Schering's counter-offer, the parties negotiated additional milestone payments for launch of Niacor-SR in nine different countries throughout the world, including \$2 million for Japan and \$1 million each for eight other countries, totaling \$10 million in milestones. CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr. 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59. (These milestones were never reached, and the payments were not made.) Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to \$50 million and a 15% royalty on annual net sales in excess of \$50 million. Troup, Tr. 5459; CX 347 at SP 12 00195.

Audibert completed his commercial assessment of Niacor-SR on June 17, 1997, one day after the final face-to-face meeting. SPX 2. Audibert and Lauda may have discussed Audibert's assessment before Audibert completed it (Lauda, Tr. 4345; CX 1483 at 30 (Audibert IH)), but the record evidence is unclear on when or how the results of the assessment were communicated to the team (Kapur, Hoffman, Wasserstein, or Thompson) negotiating with Upsher. The documentary evidence shows that Audibert's assessment was faxed to Kapur on June 17, 1997, one day after the parties agreed to the \$60 million term. Lauda testified that there was no urgency to the commercial assessment, and he did not work on it over the weekend (June 14 and 15). Lauda, Tr. 4383; CX 1515 at 103 (Lauda IH). Audibert did not have discussions with Kapur or Wasserstein before completing the assessment. CX 1484 at 103 (Audibert Dep.). Wasserstein did not recall what analysis had been completed by the time of the June 16 meeting or who told him about the financial assessment of Niacor-SR, although he recalled that the team knew the

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information and it was an assumption going forward. CX 1531 at 67-68 (Wasserstein IH). The results of this assessment are discussed below.

2. Factual Conclusions About the Negotiations

These specific findings demonstrate that, throughout the settlement negotiations, Upsher made the connection between delayed entry and the payment of money by Schering. At every negotiation session, Troup demanded compensation in return for an agreement on an entry date. Moreover, the negotiations on entry date were not concluded by June 3, 1997, and agreement on the entry date was directly linked to agreement on the other terms and conditions in the June 17, 1997 contract. Schering fully understood the essence of Upsher's demand for money in return for delay, and was aware that an outright payment for delay raised legal problems. Schering relied on the Upsher licenses to provide an ostensible justification for the \$60 million payment.

The record as a whole further demonstrates, however, that the Schering participants in the settlement negotiations (Kapur, Hoffman, Wasserstein, and Thompson) were not knowledgeable enough about the products licensed from Upsher to determine for themselves whether the Upsher licenses were worth the payments agreed upon. We now turn to the question whether, notwithstanding their unfamiliarity with the safety, efficacy, and commercial aspects of the licensed products at issue, there is other evidence from which to determine whether the Upsher licenses likely were worth \$60 million.

C. Schering's Internal Evaluation of the License Opportunities

To understand whether the license for Niacor-SR was worth \$60 million to Schering,⁸³ it is important to place the license in the

⁸³ The evidence is clear that the \$60 million payment related to Niacor-SR, and that the other products were "throw-ins" and not

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context of Schering's efforts to license another sustained-release niacin product from Kos Pharmaceuticals ("Kos") in the first half of 1997. Various Schering personnel devoted substantial time and resources to an evaluation of Kos's Niaspan product and its market opportunities. Like the Initial Decision (IDF 201-61), this section discusses both what Schering learned about sustained-release niacin during the Kos negotiations, and Schering's evaluation of the Niacor-SR license. For the reasons summarized immediately below, however, the discussion of these issues in the Initial Decision is seriously flawed and it is necessary for us to substitute our own factual findings.

The Initial Decision relies primarily on the direct testimony of two individuals – Raymond Russo, the marketing director of Schering's Key division for cardiovascular products in the United States, and James Audibert, Russo's counterpart for territories outside of the United States – for a description of the negotiations between Schering and Kos about the Niaspan opportunity. Although Russo led Schering's negotiations with Kos from February 1997 through June 1997, Audibert did not participate in the meetings with the Schering team after the end of March or early April 1997. Thus, to the extent Audibert is the source for facts beyond the date his participation ended (*e.g.*, IDF 208 and

separately evaluated as consideration for the Agreement. CX 1511 at 63 (Kapur Dep.); *id.* at 93-94 ("the deal was for Niacor"); CX 1530 at 88 (Troup Dep.); Troup, Tr. 5594-95; CX 1510 at 71-72 (Kapur IH) ("Q. Was the \$70 million value just for the Niacor license? A. Yeah. Everything else was sort of a flow in, basically for the Niacor product."); CX 1515 at 86-87 (Lauda IH) (Lauda was told that Niacor-SR's profitability would have to be enough to warrant a \$60 million up-front payment); CX 338 (presentation to Schering Board of Directors describes the other licenses as "less significant" than Niacor-SR; there is no NPV calculation for those licenses); Hoffman, Tr. 3562, 3569 (recognizing that Niacor-SR was the main licensing opportunity).

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242), the Commission has substituted its own findings from more reliable sources.

The Initial Decision also fails to consider the testimony of Driscoll, who was Russo's supervisor and was responsible for terminating the negotiations with Kos in June 1997, based on Niaspan's safety and efficacy issues and its limited commercial potential. The Commission finds Driscoll's testimony, and his memorandum dated June 9, 1997, which summarizes the commercial and product safety- and efficacy-related reasons for ending the Kos negotiations (CX 558), more probative than the deposition and direct testimony of Russo, Audibert, and Lauda (recited in IDF 207-08, 219, 242, 255, 258).

The Initial Decision also does not give adequate weight to other contemporaneous business documents that provide reliable and probative evidence of the events during the Kos negotiations. In particular, the Initial Decision does not rely on the contact reports (*i.e.*, internal summaries of the conference calls or meetings) between Schering and Kos personnel of March 13 (CX 577), April 9 (CX 1047), and May 21, 1997 (CX 557); Russo's memorandum of March 26, 1997, describing the negotiations to date and issues to be resolved going forward (SPX 21); and Audibert's March 14, 1997 questionnaire to Schering's international subsidiaries (CX 544).

Similarly, the Initial Decision fails to appreciate the implications of Schering's own market research on sustained-release niacin products (CX 576; SPX 231 (*in camera*)), and Schering's inexplicable failure to take account of that research when it evaluated Upsher's Niacor-SR product. For example, Schering's own domestic market research on sustained-release niacin in April 1997 contained nine conclusions that raise significant concerns about the commercial potential for Niaspan. CX 576. The Initial Decision's only reference to this market research is one phrase contained in one of the conclusions. IDF 211. This one statement is not representative of the other seven conclusions in the report. The Initial Decision also fails to

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consider fully what the conclusions in Schering's European market research (SPX 231 (*in camera*)) suggest about opportunities for cholesterol drugs in Europe. *See* IDF 235-36.

Schering relied heavily on the calculations of Audibert to support its claim that the payment to Upsher was reasonable, but the Initial Decision mischaracterizes the task that Lauda asked Audibert to perform. Rather than conducting "an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity" (IDF 243), Audibert simply responded to a request that he produce a sales forecast and a profit and loss statement for Niacor-SR. To the extent the Initial Decision implies that Audibert evaluated the safety and efficacy of Niacor-SR (*see, e.g.*, IDF 247), the Commission disregards it.

The Initial Decision relies on Audibert's direct testimony to prove that the Niacor-SR license was worth \$60 million, without weighing it against the knowledge that Schering had acquired through its domestic and European market research (CX 576; SPX 231 (*in camera*)) and the reservations that Schering personnel had expressed about sustained-release niacin (CX 558). *See, e.g.*, IDF 249 (discussing Schering's own market research that showed a product with a profile similar to Niacor-SR would not be well received as a monotherapy); IDF 239-41 (detail regarding what Audibert learned about the safety and efficacy of sustained-release niacin through the Kos negotiations).

Because of the Initial Decision's failure to take adequate account of various probative documents and its misplaced reliance on testimony of certain individuals, the Commission substitutes the following findings for the findings in IDF 201-61.

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1. Findings of Fact on Schering's Evaluation of Kos's Niaspan

a. Schering's Research into Kos's Niaspan Product

Kos filed an NDA for Niaspan with the FDA in May 1996. SPX 18 at 002776. Schering was interested in Niaspan in early 1997. Driscoll believed that a sustained-release niacin product "that met the unmet needs that existed in the marketplace could be big." CX 1494 at 85 (Driscoll IH); *see also* CX 1495 at 73 (Driscoll Dep); Audibert, Tr. 4116-17. Driscoll also stated that Schering was interested in niacin primarily as a complementary agent to statins, the primary pharmaceutical compounds used to treat high cholesterol. CX 1494 at 86 (Driscoll IH).

Other Schering personnel stated they were interested in Niaspan not only as a late-stage product that could generate revenues in the near term, but also because Niaspan presented an opportunity for Schering to sell a cholesterol-lowering product in advance of its launch of ezetimibe, a drug that Schering was developing for the same purpose. Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771 (Russo's memo outlining Niaspan opportunity).

In February 1997, Schering distributed to members of its Cardiovascular Licensing Group a confidential information package provided by Kos in connection with the Niaspan opportunity. SPX 924. This package contained overview information on Niaspan, a copy of its proposed labeling, and a published report of a clinical study conducted with Niaspan.

In 1997, Russo was Key's marketing director for cardiovascular products in the United States. Audibert, Tr. 4109-10; Russo, Tr. 3409-10. Russo led the negotiations with Kos on its Niaspan product. Russo, Tr. 3449. Driscoll supervised Russo. CX 1494 at 88 (Driscoll Dep.). Audibert was Russo's counterpart, responsible for territories outside the United States, and was for a time involved in the negotiations with Kos

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regarding Niaspan. CX 1483 at 77-78 (Audibert IH); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439.

By the time of Schering's negotiations with Kos, the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. Russo, Tr. 3445; Audibert, Tr. 4102, 4105. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. Russo, Tr. 3449; CX 577 at SPCID2 1A 00110 (Schering's March 13, 1997 report of contact with Kos). This arrangement differs from one in which the company that took a license would retain all control and all sales proceeds after royalties are paid. Russo, Tr. 3449-50.

Schering and Kos personnel communicated by conference call on March 13, 1997. Russo, Audibert, and Karin Gast, Director of Business Development, participated on behalf of Schering; Daniel Bell, President and CEO, and others participated on behalf of Kos. CX 577. Audibert wanted to find out whether Niaspan had a better side effect profile than immediate-release niacin, especially in the areas of flushing and itching. CX 1484 at 39 (Audibert Dep.). He also had concerns about hepatotoxicity. CX 1484 at 39-40 (Audibert Dep.). Audibert indicated that he wanted to see data from clinical studies (CX 1484 at 45 (Audibert Dep.)), and he wanted to see the charts and study reports with information on safety and efficacy. CX 1484 at 57 (Audibert Dep.). Kos did not provide this information to Schering. CX 1484 at 59 (Audibert Dep.). Audibert's deposition testimony is corroborated by Schering's contact report prepared by Gast summarizing the call, in which Audibert "in particular wanted to know what is the safety profile for Niaspan." CX 577 at SPCID2 1A 00109.

Kos's labeling also made statements about reduced risk of hepatotoxicity development with its compound, but Kos was unwilling to share any information to verify the claim. CX 1495 at 128-29 (Driscoll Dep.). Schering asked Kos for more

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information, including Niaspan's clinical results that supported the label claims. CX 1495 at 96 (Driscoll Dep.). In Driscoll's view, the data that Kos did provide Schering (CX 924) showed that the incidence of flushing in the pivotal clinical trial was too high. CX 1494 at 85-86 (Driscoll IH). In addition to the safety and side effect profile information that Schering did not receive, Schering also did not receive Kos's market research on physician interest in a sustained-release niacin product. CX 1494 at 89 (Driscoll IH); CX 1495 at 100 (Driscoll Dep.).

One day after the March 13, 1997 conference call with Kos, Audibert sent a questionnaire to Schering's international subsidiaries that inquired about their interest in sustained-release niacin and sought information about cholesterol treatment in their countries. He does not recall whether he received any responses. CX 1484 at 52-53 (Audibert Dep); CX 544. After sending this questionnaire to Schering's international subsidiaries, Audibert did not participate further in negotiating with Kos. CX 1484 at 76-77 (Audibert Dep.).

On March 26, 1997, Russo prepared a memorandum summarizing four outstanding issues that had to be resolved for the Niaspan opportunity to be viable. Russo, Tr. at 3495-96; CX 546. These included: (a) a guarantee that Schering would have input into promotional and strategic efforts; (b) an equitable method to recognize revenue; (c) due diligence regarding patent status, final labeling, manufacturing capabilities, and product liability; and (d) Schering's evaluation of the commercial potential of the product, which included an assessment of the product's worldwide potential. CX 546. Russo "assume[d] that the safety profile, levels of liver toxicity, side effects, and approved indications would be consistent with the proposed labeling included in the Kos package." CX 546 at 2770. Schering "would of course subject any deal to this [sic] criteria." CX 546 at 2770.

On April 9, 1997, Schering personnel (Russo, Toni DeMola, Gast, and David Grewcock) visited Kos Pharmaceuticals to

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discuss the Niaspan product opportunity and the issues in the March 26, 1997 Russo memorandum. CX 1047. The contact report summarizing the meeting states that Kos knew “that Niaspan will have to overcome some rather negative perceptions about niacin within the patient/medical community and that it is very important that the product get on managed care formularies.” CX 1047 at SP 002747. The contact report also notes that Dan Bell “realizes that the market potential [of Niaspan] in Europe (and probably also in Japan) is quite limited.” CX 1047 at SP 002748.

Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. Russo, Tr. 3455. Part of that process involved an assessment of the product’s value to Schering, and Russo produced three sales scenarios – a “base” case, an “upside” forecast, and a “downside” forecast for the years 1997 through 2007. Russo, Tr. 3456. He then priced each of these three scenarios under two different sets of pricing assumptions (a higher price and a lower price), so that, in total, he created six different sales forecasts. Russo, Tr. 3457; CX 550.

According to the sales forecast documents, Russo proceeded through multiple steps to arrive at the projected sales figures. CX 550. He first projected the overall U.S. population for each year, and then estimated through third-party data the percentage of patients that are likely to be managed with a prescription for lipid disorders. He then examined the total eligible patient population and how many of these patients would likely receive a prescription of any kind. He assessed what he thought Schering’s position would be in the market for niacin. He made estimates for sales and promotion to expand the market. Russo, Tr. 3458. He then determined how many patients would be treated with niacin and how many of those patients would be treated specifically with Niaspan. Russo testified that, under his most realistic scenario, projected sales in the United States were \$134 million in 2002, rising thereafter to \$193 million, based on the co-promotion deal

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under consideration with Kos. Russo, Tr. 3457-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731.

Schering's market research in the United States included efforts to determine physician interest in sustained-release niacin. Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576. A market research report entitled "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders – Telephone Interviews with Lipid Specialists" (Apr. 1997) contained nine conclusions. Six of the conclusions⁸⁴ are: (1) The 10 experts tend to be strong supporters of niacin, as opposed to general practice physicians that tended to avoid niacin. These experts point out that niacin "does all the right things" to manage lipids. (2) The experts avoid use of sustained-release niacin because of diminished efficacy and concern regarding liver toxicity. The experts pointed out that successful use of niacin requires a very motivated physician as well as patient, and that expanding niacin use will require a major commitment to physician and patient education. (3) Most niacin use is in combination with a statin, which has become the mainstay of lipid management, but several experts commented that this adjunctive role may lessen as new products are used. (4) The fibric acids (a competitor to niacin) are widely used in Europe, and several physicians reported being quite impressed with fenofibrate. (5) Although the experts would welcome an effective, safe, FDA-approved sustained-release niacin, the single study Schering discussed with them did not sell them on Niaspan and they needed larger, longer studies and trials in combination with a statin to be convinced on the safety issue. (6) Physicians voiced numerous concerns and questions about safety, side effect claims, and use with a statin, and they need "compelling evidence" to support the safety and side effect claims, which "go against our experience" with niacin. A

⁸⁴ The other three conclusions discuss the relative merits of altering levels of particular components of total lipids as treatment methods.

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successful sustained-release niacin product will take time and “a significant promotional investment.” CX 576 at SP 020709-12.

In the spring of 1997, Audibert began coordinating with Schering’s European subsidiaries to establish an advisory panel with European experts in cholesterol management to obtain market research about its cholesterol drug in development – ezetimibe. Audibert, Tr. 4301-02 (*in camera*); SPX 221 at SP 002895-2898 (*in camera*). This panel concluded that a large market for the product does not exist unless it is “very inexpensive and very safe.” SPX 231 at 002949.

b. Termination of Schering’s Negotiations with Kos

On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. Russo, Tr. 3463-64; CX 554 (*in camera*); SPX 619. Schering is the only company that gave Kos a written proposal before Niaspan was launched. Patel, Tr. 7543. Schering proposed to Kos a co-promotion arrangement in which both companies would sell and market the product together. Russo, Tr. 3589 (*in camera*); CX 554 (*in camera*). Schering proposed a 50/50 profit and loss split (Russo, Tr. 3589-90 (*in camera*); CX 554 (*in camera*); Patel, Tr. 7665 (*in camera*); SPX 619 (*in camera*)) and also suggested that it would give Kos a 10% to 15% royalty payment on the total sales of its product. Russo, Tr. 3589-90 (*in camera*); CX 554 (*in camera*). One week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. SPX 230; SPX 35 (*in camera*); Patel, Tr. 7667 (*in camera*). Kos did not react favorably to Schering’s proposal. Russo, Tr. 3465. Bell, the Chief Operating Officer of Kos, told Schering representatives that its offer was practically “insulting,” and that he was “offended” by it. SPX 230; Patel, Tr. 7669 (*in camera*). A major problem for Kos was Schering’s failure to offer an up-front payment. Kos also wanted very significant milestone payments, to compensate for its research and development costs, and to reassure Kos that Schering was committed to the venture. Patel, Tr. 7531-32; CX 556 (*in camera*); CX 769 (*in camera*); Russo, Tr. 3465-66. After

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receiving Kos's reaction to its first proposal, Schering did not submit another proposal. Russo, Tr. 3466, 3488; CX 558.

On June 9, 1997, Driscoll recommended to his superior, Richard Zahn, that Schering discontinue discussions with Kos. CX 558. Driscoll explained in the memorandum that "the principal reason" for discontinuing negotiations was that the opportunity was not large enough to warrant distraction from Key's core businesses. He did not share the view of the outside investment analysts who indicated that the Kos product was a \$250 million product. He estimated a peak year of \$134 million in 2002 with a 10-year net present value of \$420 million. Driscoll pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduced niacin side effects of flushing and hepatotoxicity. He noted that Niaspan's labeling "indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing." CX 558 at 2719. He also explained that statins have taken a large share in the market, and that generic statins would be available in the U.S. in 1999, which could affect sales of a lower-priced niacin product such as Niaspan. Driscoll concluded there was a wide gulf on expectations. CX 1495 at 123-24 (Driscoll Dep.).

2. Findings of Fact on Schering's Evaluation of Upsher's Niacor-SR

In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product that would cost Schering approximately \$60 million, and asked if Global Marketing would perform an assessment of the product. Lauda, Tr. 4342-43. It is unclear from the evidence how Kapur knew that the licensing opportunity would cost \$60 million. Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide Ex-NAFTA"). Lauda, Tr. 4344.

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Audibert was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. Audibert, Tr. 4085, 4092. His responsibilities included work on ezetimibe, the cholesterol-lowering agent Schering had in development. Audibert, Tr. 4093. By early 1997, Audibert began working with Schering's research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. Audibert, Tr. 4094. As part of this process, Audibert was also evaluating the market for cholesterol-lowering drugs. Audibert, Tr. 4094-95.

Lauda specifically asked Audibert to develop a sales forecast and a profit and loss statement for Niacor-SR based on the information provided in a 52-page data package. CX 1484 at 109-10 (Audibert Dep.). Audibert began his review when he received this data package on Niacor-SR on Thursday afternoon, June 12, 1997, and completed his work on Tuesday morning, June 17, 1997. Audibert, Tr. 4113, 4163; Lauda, Tr. 4344-45. The package included summary results from the two phase III pivotal clinical trials conducted by Upsher to obtain registration of Niacor-SR. Audibert, Tr. 4113-15, 4171; CX 1042; Halvorsen, Tr. 3907-08. The package also included information on two draft protocols for phase III-B studies that Upsher was planning to conduct once the NDA was filed. Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025. One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. Audibert, Tr. 4115; SPX 71-72.

The clinical data from Upsher's pivotal trials showed that Niacor-SR reduced LDL cholesterol between 15% and 20%. Audibert, Tr. 4123; CX 1042 at SP 1600082, SP 1600097. This reduction is comparable to that resulting from use of Niaspan. CX 924 at SP 002789, SP 002792. Both the Niacor-SR and Niaspan reductions exceeded the 15% regulatory hurdle, but were less than the 20% reduction that Schering's market research indicated would be necessary to market the product as a monotherapy. SPX 231 at 002944-45 (*in camera*). Upsher's summary clinical data

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for Niacor-SR showed that the overall incidence of flushing was comparable to that of Niaspan. *Compare* SPX 3 at 160088 (on Niacor-SR) *with* SPX 924 at SP 002809 (on Niaspan). Moreover, the Upsher data showed that even though the number of flushing occurrences was lower, on a per patient basis, than with immediate-release niacin (*see* SPX 3 at 16 00089 (graph at top of page) and Audibert, Tr. 4118-19), the occurrences were just as severe as those experienced among patients taking immediate-release niacin. SPX 3 at SP 16 00088 (graph at top of page).

The clinical data from Upsher's pivotal trials showed that adverse effects on the liver increased with stronger doses of Niacor-SR. CX 1042 at SP 1600090; CX 1483 at 73-74 (Audibert IH). Audibert testified that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that of cholesterol-lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained-release niacin products. Audibert, Tr. 4104-05, 4121-24. Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. Audibert, Tr. 4121-22; CX 1042 at SP 16 00093. These results are comparable to the information that Schering had when it had evaluated Kos's Niaspan product. *See* SPX 924 at SP 002811.

Audibert constructed a forecast of sales based on the product's profile in the market. Audibert, Tr. 4124. The process for constructing this sales forecast included: (1) a determination of the current and future sizes of the cholesterol-lowering market; (2) a determination of how Niacor-SR would be positioned within that market; (3) a determination of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. Audibert, Tr. 4124-27.

First, Audibert determined the current size of the market and made a projection of the future growth of that market for a period

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of 10 years based on IMS data representing the current size of the cholesterol-lowering market worldwide, excluding the U.S., Canada and Mexico (“Worldwide Ex-NAFTA”), the territories in which the license to Niacor-SR was available. SPX 5; CX 1483 at 109-10 (Audibert IH). The IMS data indicated that the size of the cholesterol-lowering market in those territories in 1996 was \$4 billion. SPX 5. Audibert’s handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. SPX 5 at SP 16 00447. Audibert estimated an average annual growth of 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. SPX 2 at SP 16 000046. Audibert projected the market share Niacor-SR could achieve based on his experience with this type of product and this type of profile, given the existing competitive landscape. CX 1483 at 100-02 (Audibert IH). Audibert believed that Niacor-SR would obtain an initial market share of only .75%, rising for just two years to 1.5%, and then decreasing thereafter to 1%. Audibert, Tr. 4127-29; SPX 2 at SP 16 00047.

Having estimated the overall size of the market and a market share for this product over a 10-year period, Audibert used multiplication to determine projected sales. Audibert, Tr. 4127. Audibert’s formal written assessment for Niacor-SR, dated June 17, 1997, includes tables illustrating his annual projections of market size and market share, from which he calculated annual dollar sales. Audibert, Tr. 4127-29; SPX 2 at SP 16 00046-47. The sales projected for each of these years, in millions, were:

Sales (\$)	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Millions	45	70	114	126	116	127	140	125	136	149

SPX 2 at SP 16 00047.

On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. Audibert, Tr. 4138-39; SPX 6. The annual profit and loss calculations were created by deducting

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the cost of goods sold (estimated at a standard 10% of sales) from his sales forecasts (CX 1483 at 115-16 (Audibert IH)), as well as deducting the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at \$22.8 million in the third year of sales. SPX 6. Because Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher. Audibert, Tr. 4139.

After Audibert developed the commercial assessment (SPX 2; SPX 6), he summarized the information contained in the 52-page data package without independently verifying it. CX 1483 at 95-96 (Audibert IH). Audibert provided background information on cholesterol-lowering products, including the current state of knowledge on niacin as an effective cholesterol-lowering agent, as well as the difficulties that had hampered prior immediate-release niacins (flushing) and sustained-release niacins (association with hepatotoxicity). SPX 2 at SP 16 00041-45. Audibert detailed the current size of the cholesterol-lowering market and the recent growth experienced in that market, and provided an assessment of why that growth was expected to continue. SPX 2 at SP 16 00043-45. He concluded that a product opportunity existed for Niacor-SR, and he provided a summary of his sales projections for Niacor-SR. SPX 2 at SP 16 00045. He attached to his assessment two tables that contained his detailed financial projections of both the future growth of the cholesterol-lowering market and sales of Niacor-SR in that market. SPX 2 at SP 16 00046-47. Audibert concluded that Niacor-SR offered a \$100+ million sales opportunity for Schering. SPX 2 at SP 1600045. He provided a copy of each of these documents to Lauda. Audibert, Tr. 4138-40; Lauda, Tr. 4345-46.

On the basis of the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher called for under the agreement, Wasserstein prepared a presentation for the Schering Board. SPX 26. The presentation included a calculation which indicated that Niacor-SR yielded an economic value to

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Schering of between \$225 to \$265 million, and an internal rate of return of 43%. SPX 26 at SP 16 00275.

3. Factual Conclusions on Schering's Investigation of Niaspan and Niacor-SR

We do not find that Schering's failure to pursue the Kos opportunity is conclusive evidence that it was not really interested in the Upsher product. There were deal-specific reasons that contributed to Schering's rejection of the Kos co-promotion opportunity. However, the Kos negotiations did inform several Schering personnel about the commercial problems of sustained-release niacin products – information that we need to weigh in determining whether Schering really paid \$60 million for the rights to such a product.

Schering's decision to decline an opportunity to co-promote Kos's Niaspan product was made only the week before the negotiations for Niacor-SR were completed on June 17, 1997. Driscoll's June 9, 1997 memorandum to his supervisor, Richard Zahn (on which he copied all of the members of Schering's Kos negotiating team), recommended that Schering discontinue negotiations with Kos and described these commercial problems in detail. CX 558. Driscoll wrote that "the principal reason" for discontinuing the negotiations with Kos was "based on our current assessment that Niaspan does not represent a large-enough opportunity in the marketplace, thus, sufficient revenues would not be available to Schering-Plough to warrant our involvement and distraction from our core businesses." CX 558 at 2719; *see also* SPX 56. Driscoll calculated the NPV based on the co-promotion proposal for the U.S. market and found that the expected gain would not warrant Schering's involvement, even "without consideration given to the 'lost opportunity sales' we would experience with our current brands due to our shift in

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promotional focus away from these products to support the marketing of Niaspan.” CX 558 at 2719.⁸⁵

Driscoll then evaluated the commercial opportunity for niacin in a market increasingly dominated by statins. Lipitor had been introduced and had a “torrid start.” CX 558 at 2720. Based on Lipitor’s potency and “seemingly benign side-effect profile,” Driscoll stated that the need for a niacin product in combination with another cholesterol-lowering product was “greatly reduce[d].” CX 558 at 2720. According to the memorandum:

Niaspan could be relegated to the severe hypercholesteremic patients who need a multiple drug regimen. *As a result, Niaspan’s market opportunity is narrowing even prior to its introduction.* Indeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor.

CX 558 at 2720 (emphasis added).

Although the deal contemplated with Kos was not exactly the same as the deal with Upsher – the Kos deal was to be a cross-promotion, where Kos and Schering would split the profits – Schering’s view that the product had limited potential in the U.S. market transcends the specific terms of these deals. Driscoll

⁸⁵ IDF 221-26 suggest that Kos was unable to enter into an agreement with a licensing partner because Kos’s demands were unreasonable. Whatever the truth of the proposition that Kos was aggressive in its negotiations with potential partners, Kos has not been able to license Niaspan to any ex-U.S. partner, much less obtain an agreement as lucrative as the Upsher/Schering agreement. Patel, Tr. 7540. Moreover, Schering’s primary reason for terminating its own negotiations with Kos was concern about the sales prospects of Niaspan – and it was not alone in these concerns. Egan, Tr. 7913-14 (Searle’s view).

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pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduces niacin side effects, flushing and hepatotoxicity. He stated that “it is important to note” that Niaspan’s labeling “indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing.” CX 558 at 2719; SPX 924 at SP002809.⁸⁶

Upsher’s summary clinical data for Niacor-SR showed that reduction in cholesterol and the incidence of flushing were comparable to those for Niaspan. Schering’s pharmaceutical expert, Dr. Zola Horovitz, testified that the summary tables in the 52-page data package show that Niacor-SR was more effective than immediate-release niacin (Horovitz, Tr. 3642-43), and more benign than immediate-release niacin in terms of flushing (Horovitz, Tr. 3645-46) and liver enzyme elevation. Horovitz, Tr. 3632-35, 3649-51. It would be more appropriate, however, to compare Niacor-SR with Niaspan and specifically to take account of what Schering personnel who had worked on Niaspan believed were its commercial prospects. Driscoll’s June 9, 1997 memorandum, discussed above, is a credible expression of their view, and we find that their expressed reservations about the safety and efficacy of Niacor-SR are more persuasive than Dr. Horovitz’s opinions.⁸⁷

⁸⁶ By comparison, the summary clinical data that were provided to Audibert showed flushing incidence of 87%, 81%, and 87% for three different dosages of Niacor-SR. SPX 3 at 16 00088; Audibert, Tr. 4118 (explaining that column A is for immediate-release, while B, C, and D are Niacor-SR dosages).

⁸⁷ Upsher, too, recognized that the market opportunity for a sustained-release niacin product was narrowing. In March 1997, Upsher noted that the “total niacin market has been relatively flat in dollars while increasing 35% in units.” CX 929 at USL 13138. In fact, the sustained-release niacin market had “declined 14% from the previous year” in dollar terms, and 7.7% in volume terms. *Id.*

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One incident in the course of Schering's discussions with Kos is also particularly probative. Schering personnel saw the U.S. market as more appealing than the European market, for which Schering later obtained the Niacor-SR rights. According to a Schering summary of a meeting with Kos on April 9, 1997, Schering recommended that it made sense to focus on the U.S. market first and hold off on ex-U.S. talks:

Global option: we suggested that, since time is of the essence in the U.S., we concentrate on this territory first and leave ex-U.S. discussions for later. [Kos CEO] Bell did not have a problem with this. He realizes that the market potential in Europe (and probably also in Japan) is quite limited.

CX 1470 at SP 002748(DeMola/Russo memorandum dated 4/9/97). As this memorandum makes clear, both Kos and Schering shared the view that the European market for this type of product was less commercially appealing than the U.S. market.⁸⁸

Schering's careful scrutiny of the Kos opportunity also shows the type of information Schering personnel thought was necessary for a prospective partner to provide before proceeding with a commercial opportunity for a sustained-release niacin product. In his memorandum explaining the reasons for declining the Kos opportunity, Driscoll wrote that Kos had not been forthcoming with important data necessary to fully evaluate the deal, such as its sales projections for Niaspan and "results from physician primary research conducted by Kos." CX 558 at 2720. Yet Schering did not even request sales projections or primary research relating to Niacor-SR from Upsher.

Similarly, Russo's memorandum of March 26, 1997, which set out the hurdles that needed to be cleared before an opportunity with Kos could be finalized, concluded that "[f]or this [Niaspan]

⁸⁸ Searle also shared this view. Egan, Tr. 7915-16.

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opportunity to be viable for [Schering] a number of issues must be resolved,” including “due diligence validation of issues” such as patent status, finalized labeling, manufacturing capabilities, and product liability. SPX 21 at 002770. Schering would also “need to independently assess this product’s world-wide potential,” including “global potential, Managed Care impact, and strategic synergy with 58235 [a product then in development], and field force availability/fit.” SPX 21 at 002771. Aside from Audibert’s projection of Niacor-SR sales, none of these tasks were undertaken with respect to Niacor-SR. Moreover, Russo “assume[d] that the safety profile, levels of liver toxicity, side effects, and approved indications would be consistent with the proposed labeling included in the Kos package. *We would of course subject any deal to this [sic] criteria.*” SPX 21 at 002770 (emphasis added). By contrast, Schering’s agreement with Upsher was not conditioned on validation of any representations or on any regulatory benchmarks.

Schering’s own domestic market research showed that physicians had numerous concerns and questions about the safety, side effect claims, and use with a statin of sustained-release niacin. Physicians also needed “compelling evidence” to support the safety and side effect claims that “go against our experience” with niacin. The research showed that a successful sustained-release niacin product would take time and “a significant promotional investment.” CX 576 at SP 020709-12.

Lauda had given Audibert, who had participated only briefly on the Schering team that evaluated Niaspan, the task of estimating Niacor-SR sales. The work that Audibert did to arrive at his sales forecasts was not nearly as extensive or as refined as the work that Russo did in his sales forecasts of the Niaspan opportunity with Kos. Russo based his sales forecasts on an analysis of the eligible patient population within the U.S., whereas Audibert used aggregate ex-U.S. sales as his starting point. Audibert did not examine eligible patient populations on a country-by-country basis as Schering’s expert witness, James Furniss, testified he would have expected Schering to do. Furniss, Tr. 4273. Furniss testified

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that a more detailed, country-by-country analysis of a late-stage product such as Niacor-SR is important because each country has a different pricing reimbursement system and some products may be widely prescribed in one country and not in another. Furniss, Tr. 4270-71. Moreover, in contrast to Russo, who had prepared six different forecasts under various pricing assumptions for Niaspan, Audibert prepared only one sales forecast with no allowances for different market penetration statistics or pricing scenarios.

Audibert received the Upsher materials on which he based his commercial assessment no earlier than 4:30 p.m. on Thursday, June 12. He faxed the completed commercial assessment and profit and loss statement on Tuesday, June 17, at 9:30 a.m. Audibert said that the tasks he performed would take “maybe a little bit more but not – not much more” than one day to complete. Audibert, Tr. 4164. During this 5-day period Audibert did not contact personnel at Upsher to determine when the draft protocols would be started or completed, or to request the labeling for the product. Audibert, Tr. 4172-75; CX 1484 at 91-92 (Audibert Dep.). He did not contact any members of the Schering team that had just terminated discussions about Niaspan with Kos on June 9, 1997. CX 1483 at 50-52 (Audibert IH); Audibert, Tr. 4168. Instead, he based his commercial assessment on the information about Niacor-SR provided to him by Upsher. Audibert did not independently verify any of the information in the 52-page data package. He said that he based his assessment on what the product would be (*i.e.*, labeled for once-a-night dosing and administered in combination with other cholesterol products), not on what clinical tests had been done so far. Halvorsen, Tr. 4025; CX 917 at 107435; Audibert, Tr. 4172-76, 4196-97. He simply assumed that Niacor-SR would be approved for these indications even without completion of the additional clinical tests. Audibert, Tr. 4173.

These assumptions stand in direct contrast to Audibert’s skepticism about the Niaspan product, for which he and Driscoll

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had demanded additional information to verify Kos's claims.⁸⁹ He was more cautious about Niaspan, even though Kos was much further along in obtaining approval for the indications that were of interest.

Based on the record as a whole, we find that Schering knew sustained-release niacin had significant unresolved safety issues, limited market appeal in the U.S., and even less outside of the U.S. Even if we assume that Schering had only five days to review the Niacor-SR product,⁹⁰ it could have done much more – in parallel with Audibert's work on the commercial sales projection – to ascertain whether Niacor-SR merited such a substantial, unconditional investment. For example, nobody at Schering was assigned to evaluate the likelihood of obtaining regulatory approval for Niacor-SR in the U.S. or in Europe, to examine Upsher's regulatory file quickly, to inquire into the strength of the patents contained in the 52-page data package, to determine whether there was European patent protection, to have the specialists at the Schering-Plough Research Institute do a preliminary safety analysis, or even simply to ask Upsher whether the FDA had raised any regulatory hurdles.⁹¹ There is no reason

⁸⁹ The 52-page data package that Upsher provided to Schering contained information that is similar to what Kos had provided to Schering regarding the Niaspan opportunity. CX 1042 at SP1600081-85, 94; SPX 924.

⁹⁰ We recognize that the parties wanted to settle the case before the trial commenced, although it is not clear why this was an essential pre-condition for settlement. Many cases settle in the course of a trial.

⁹¹ There were regulatory hurdles. The FDA had raised issues about Niacor-SR's dosing regimen and the need for a pharmacokinetic test. Niacor-SR was to "be labeled to take with meals," CX 917 at 107435, contrary to the assumption in materials provided to Audibert that it would be once-a-night

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why the materials submitted by Upsher could not have been circulated both to Audibert and to technical, scientific, regulatory, and patent professionals for an initial, even if hurried, review.

We recognize that significant time constraints may often require a very compressed review of potential products that would fall far short of the formal due diligence that a company would otherwise conduct, given adequate time. Schering's failure to conduct formal due diligence does not, in itself, mandate a conclusion that the side deal for Upsher licenses was a pretext to mask the payment of substantial consideration for a deferred entry date.⁹² However, Schering's minimal analysis of the Niacor-SR opportunity must be weighed heavily, along with the other facts in this case, as we determine whether Schering paid \$60 million for licenses or for delay.

D. Inferences Derived from Conduct After the Settlement

The Initial Decision concluded that there was "substantial, reliable evidence to explain Respondents' post-deal conduct and attendant decisions not to pursue Niacor-SR." ID at 109. This conclusion, however, is based more on a quantitative count of individual communications between Schering and Upsher than on

dosing. Upsher had been having trouble for some time developing the pharmacokinetic test, which profiles the rate and extent of absorption of a drug in the body (Audibert, Tr. 4181). That test's validation method was not completed until November 4, 1998. Halvorsen, Tr. 3943-44; SPX 333 at 165879.

⁹² We reject any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table when such a review concludes. We therefore do not rely on Dr. Levy's opinion about the acceptable parameters of due diligence. However, our own findings show there was ample record evidence to support a conclusion that Schering's analysis of the Niacor-SR opportunity was perfunctory.

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their substance. (IDF 263-66, 271-74, 279, 280, 282, 284, and 287-89 review the post-agreement communications between the parties from June 24, 1997 to September 24, 1998.)⁹³ A closer examination of the content and context of these communications reveals that most of them concerned matters necessary to *initiate* a relationship between the parties – such as confidentiality agreements and proposed amendments to the Settlement Agreement – rather than substantive matters. In fact, the parties did not communicate at all about substantive issues as important as Upsher’s decision to put development of Niacor-SR on hold and its later decision to terminate Niacor-SR development altogether – decisions that essentially suspended and then wiped out the benefits that were ostensible consideration for Schering’s \$60 million payment.

In fact, there were virtually no substantive communications about Niacor-SR, the key licensed product. For example, IDF 282 notes that “[d]uring 1998, Upsher remained in contact with Schering-Plough regarding the licensed products” and cites four documents: CX 1088, CX 1111, SPX 251, and USX 665. CX 1088 was an aggregate of other documents; the only document included in this aggregate dated after 1997 was a copy of Upsher’s October 6, 1998 letter (CX 1111) announcing the termination of its work on Niacor-SR. The other two cited documents are a January 1998 draft of the Manufacturing Agreement (USX 665) and an April 1998 letter from Ray Kapur’s secretary (SPX 251) enclosing signed confidentiality agreements, a preliminary step in the relationship that took 10 months to complete after the Agreement was signed.

⁹³ In addition to written communications, there were also some, but few, conversations between Schering and Upsher employees. IDF 316 records at least two meetings and 21 other documented communications between Schering and Upsher in 1997 after the licensing agreement, as well as some telephone calls.

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Many of the communications that did take place concerned tasks that were never accomplished. For example, Schering and Upsher exchanged correspondence and drafts relating to a Manufacturing Agreement that concerned such issues as the supply and delivery of the licensed products. SPX 255; Kralovec, Tr. 5050-55; USX 732; SPX 217; SPX 251 (Jan. 1998). The proposed Manufacturing Agreement was dropped, and there was no further correspondence on the subject after January 1998. USX 665.

The few requests that Schering did make for information about Niacor-SR went unfulfilled, and Schering did not continue to request the information. For example, in response to a Schering request for information on Niacor-SR, Troup agreed that Upsher would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) was completed. IDF 265; SPX 10; SPX 12 at SP 05 00013; Audibert, Tr. 4156. However, Audibert received only the protocols, and did not renew his request for information on Niacor-SR thereafter. Audibert, Tr. 4142, 4149-50, 4154-57, 4360; SPX 251.

There is virtually no correspondence about the key question in which Schering had such a substantial stake: the progress of Niacor-SR's development and the NDA. From November 12, 1997, to September 24, 1998 – when Upsher disclosed that it was no longer developing Niacor-SR – Schering and Upsher exchanged a total of two communications even though Upsher was to have submitted the NDA for Niacor-SR to the FDA in October 1997. USX 665; SPX 251. Of these two communications, only one arguably touched upon the status of Niacor-SR – an April 20, 1998 letter from the secretary of Ray Kapur, the head of Schering's Warrick generic division. SPX

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251.⁹⁴ In a cover letter, Desiree Malanga enclosed executed confidentiality agreements, asked for a status report on the generic Pentoxifylline dossier, and then asked “in addition” that Upsher provide “complete information” on Niacor-SR to Thomas Lauda. SPX 251. This request for information on Niacor-SR was not honored, and Schering did not follow up. Audibert, Tr. 4156-57, 4360.⁹⁵

The Initial Decision’s findings highlight the impact of the disappointing sales of Kos’s Niaspan on the parties’ decisions about Niacor-SR. IDF 275-81. IDF 275 states that Kos’s sales were below what “everyone” had expected. Neither Schering nor Searle had adopted the analysts’ inflated projections for Niaspan. CX 558; Egan, Tr. 7913. Moreover, the Initial Decision ignores the clear evidence that in August 1997, well before Niaspan’s sales were announced in November, Upsher was considering the abandonment of Niacor-SR (CX 1357) – primarily because of Niaspan’s superior clinical profile and earlier entry. *See, e.g.*, CX 930 at USL 13192; CX 963 at 12583, 12581; CX 1357. When Upsher explained its reasons for terminating the development of Niacor-SR to Schering in 1998 (CX 1111), Kos’s sales were a secondary reason for dropping the program.

In addition to significant errors of omission, the Initial Decision relies heavily on unreliable evidence and ignores other evidence that is more reliable. For example, the findings in the Initial Decision that deal with Upsher’s termination of Niacor-SR place great weight on the self-serving, after-the-fact testimony of individuals like Audibert, Troup, and Lauda, which emphasizes

⁹⁴ The other communication was a January 12, 1998 draft of the never-finalized proposed Manufacturing Agreement. USX 665.

⁹⁵ Halvorsen testified that Upsher did provide some information on Pentoxifylline in response to this request. Halvorsen, Tr. 3980-82.

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the impact of Niaspan sales. The findings ignore contemporaneous business documents, which make it clear that disappointing sales were a subsidiary consideration. We believe that the documents are more credible.

Because of these errors and omissions in the Initial Decision, the Commission substitutes the following findings for IDF 262-89:

1. Findings of Fact on the Post-Settlement Conduct of Schering and Upsher

On July 2, 1997, eight days after Schering's Board of Directors approved the Niacor-SR license on June 24, 1997 (CX 340), Kapur informed Cesan that Global Marketing would take responsibility for Niacor-SR, while Warrick, Schering's subsidiary, would oversee development of the generic products licensed from Upsher.⁹⁶ SPX 8. At the same time, Kapur notified Lauda that the Niacor-SR deal had been approved and that Global Marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. SPX 7; Lauda, Tr. 4349-50. James Audibert, the Global Marketing division employee whom Schering selected as designated project leader for Niacor-SR, testified at trial that he had been appointed to coordinate the preparation of the dossier for international filing. Audibert, Tr. 4140. Audibert testified in his investigative hearing, however, that he did not know what a "designated project leader" was for Niacor-SR, that he was not sure there was one, and finally that he assumed he was it *de facto*. CX 1483 at 123-24 (Audibert IH). He did not recall that Global Marketing had been assigned responsibility for registration of Niacor-SR in Europe; this assignment confused him because "global marketing is not

⁹⁶ Schering's United Kingdom subsidiary declined the Niacor-SR opportunity and informed Upsher's consultant that the opportunity had been passed on to Schering's International Division, which to that date had not responded. CX 1363.

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responsible for registering products.” SPX 7; SPX 8; CX 1483 at 121-23 (Audibert IH). He did not believe that he was responsible for development and registration work for Niacor-SR, and did not work on it. CX 1484 at 1670-71 (Audibert Dep.); CX 1483 at 124-25, 127 (Audibert IH).

After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. Troup, Tr. 5481-83. By the end of July, Upsher and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher. USX 732. As of the summer of 1997, Upsher was going forward with its NDA for Niacor-SR and Upsher’s primary activity was to complete the final study reports and the ISS/ISE. Halvorsen, Tr. 3975. The patient phases of all four clinical studies had concluded before June 1997 and Upsher was in the process of compiling the data. Halvorsen, Tr. 3912. These agreements, as well as the ISS/ISE, were never completed.

During June and July 1997, Upsher was working on its Niacor-SR package insert to include with its NDA submission. Freese, Tr. 4990; USX 308. By July 21, 1997, Upsher had developed a revised draft of its package insert. Freese, Tr. 4990; USX 308. Upsher’s draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. Freese, Tr. 4990; USX 308 at 110477-9. The package insert was never shown to Schering.

Before August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data (in the first of several communications between the two representatives). Halvorsen, Tr. 3976-77; USX 189. During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher had conducted with Niacor-SR for FDA approval – the two pivotal studies and the two follow-on studies. Halvorsen, Tr. 3976-77; USX 189. On August 14, 1997,

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Audibert sent Halvorsen a fax to arrange a meeting at Upsher for the week of September 15. USX 189. That meeting never took place.

Halvorsen testified that in August 1997, Upsher was still planning to file its NDA for approval of Niacor-SR at the end of 1997. Halvorsen, Tr. 3977-78. Halvorsen told Audibert that he did not believe that clinical data would be available until late October, and that what Upsher would have at that time were the final reports from the individual studies, and not the ISS/ISE. CX 780 at 00236. Schering was not told that Upsher was simultaneously considering the abandonment of all work on the Niacor-SR NDA in light of the approval of Kos's Niaspan on July 28, 1997. An August 12, 1997 Upsher memorandum "review[ed] recent changes in the marketplace that may significantly impact the potential marketability of the *Niacor SR* product." CX 1357 (emphasis in original). Kos's product would use once-a-night dosing to minimize flushing, while Niacor-SR was to have twice-a-day dosing. *Id.* According to the memorandum, "It appears that *Niacor SR* will have a similar clinical profile versus *Niaspan* as it relates to the reduction of LDL, however *Niaspan* has a decided advantage on the reduction of Triglycerides, and the increase of HDL. *Niacor SR* also seems to [. . . affect] Lipoprotein more significantly than *Niaspan*." CX 1357 at 11931 (emphasis in original). Niacor-SR "will be a late entry into the Lipid Management category. Based on the information at hand it would seem that the product would also be inferior to the *Niaspan* product. Approval of the present form of *Niacor SR* is not eminent [sic] and may face delays." *Id.* at 11932 (emphasis in original).⁹⁷ Upsher did not terminate the program at that point, but

⁹⁷ Halvorsen testified at trial that the August 12, 1997 memorandum mistakenly indicated that Upsher would "need to conduct further studies to enable Niacor SR to be marketed with indications similar to Niaspan," at additional cost and delay. Halvorsen, Tr. 3950-52, 3957-60; CX 1357 at 11932. As it turns out, Upsher found out after August 1997 that the FDA had

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did decide in October to devote “minimal activity” to the Niacor-SR NDA. CX 963 at 12579-81.

In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States. Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480. The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos’s stock price, which had peaked around \$44 per share, plummeted to \$5 per share.⁹⁸ Troup, Tr. 5480. By that time, however, Upsher had already decided to devote only “minimal activity” to Niacor-SR, primarily because of Niaspan’s superior clinical profile, additional indications, and earlier entry. *See, e.g.*, CX 930 at USL 13192; CX 963 at 12579-81; CX 1357. Upsher’s letter to Schering, stating its reasons for terminating the development of Niacor-SR, makes clear that Kos’s sales were a secondary reason for dropping the program. *See* CX 1111 (Kralovec writes that the Kos sales results “reinforced” the decision).

According to Troup, an unidentified person at Schering informed Upsher in March 1998 that Schering was no longer

suggested those indications on the basis of general experience with niacin, not on any “outcome studies” conducted by Kos. Halvorsen, Tr. 3950-52. Ironically, Schering was aware that these additional indications for Kos’s Niaspan product had been suggested by the FDA. SPX 22 at 2746. Upsher did not contact Schering to clarify Upsher’s mistaken impression, nor did Upsher attempt to clarify this question with the FDA. Regardless, Upsher’s struggles with development of the pharmacokinetic test validation method and completion of the ISS/ISE show that the memorandum was prescient when it concluded that Niacor-SR approval was not imminent.

⁹⁸ Schering had not shared the analysts’ overly simplistic projections for Niaspan sales, nor had Searle. SPX 47; Egan, Tr. 7913-14.

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interested in marketing Niacor-SR outside the U.S. Although Halvorsen and Troup both were present at the meeting where Upsher decided to discontinue further work and wrap up in an unfinished state the contract research that Upsher had begun with third-party research firms, neither recalled who at Schering called with this important information, or even who at Upsher received the communication. Halvorsen, Tr. 3925; Troup, Tr. 5608-09. The information was never confirmed in writing. As noted above, the parties exchanged only two written communications in all of 1998 before the termination. USX 665; SPX 251.

In September 1998, Troup, Audibert, and Kapur had a telephone conversation about the status of Niacor-SR. Audibert, Tr. 4158-59; CX 1088 at 006-7. Troup reported that Upsher was not planning to file its NDA for FDA approval. CX 1088 at SP 05 006-07; CX 1111. In this conversation, Troup explained that Niaspan appeared to be marginally better than Niacor-SR. CX 1088; CX 1111; *see also* SPX 15 at 00057 (Audibert's September 1997 memo to Lauda on this discussion). Upsher believed that because Niaspan had received indications (*i.e.*, FDA approval) for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those same indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60. Upsher also believed that Niaspan was superior in other ways, aside from the additional testing Upsher mistakenly believed Kos had performed. *See, e.g.*, SPX 15 at 16 00057; CX 930 at USL 13192; CX 1097; CX 1357.

For its part, Schering discontinued efforts to bring Niacor-SR to market for several reasons. Audibert, Tr. 4144-45; Lauda, Tr. 4352. As set out in Audibert's memorandum, first, Upsher believed that "Niaspan is a marginally better product than Niacor-SR in terms of safety and efficacy." CX 1088 at 05 0006. Second, Audibert noted that "in August '98, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." SPX 15 at 16

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00057. The fact that Upsher had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together an international dossier than had originally been anticipated. Audibert, Tr. 4145; SPX 15. Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. Audibert, Tr. 4145.

As Kapur had requested on October 6, 1998, Paul Kralovec, Upsher's Chief Financial Officer, provided written confirmation of Upsher's decision to suspend its efforts on Niacor-SR. CX 1111; Kralovec, Tr. 5057; Lauda, Tr. 4428-29. In the letter, which was also copied to Troup, Kralovec again confirmed the reasons for Upsher's decision not to proceed with U.S. approval. CX 1111. Kralovec's letter based that decision "first and foremost" on FDA's requirement that Upsher complete a pharmacokinetic study, with Kos's sales performance a secondary consideration. CX 1111.⁹⁹

Neither Troup in the September 1998 telephone call, nor Kralovec in his October 1998 written confirmation, mentioned to Schering the mysterious March conversation in which someone from Schering had supposedly stated that the company did not plan to market the product outside the U.S. SPX 15; CX 1111.

⁹⁹ The memorandum stated three reasons for Upsher's decision to discontinue the NDA, last of which is Niaspan's sales: (1) Upsher was "focusing their efforts in defending their generic amiodarone against AHP, (2) based on the clinical data, the profile of Niacor seems to be slightly inferior to Niaspan (Kos), and (3) the Kos product has not been successful in spite of Kos investing considerably more sales and promotional efforts than Upsher intended to do." SPX 15 at 1600057.

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2. Factual Conclusions About Post-Settlement Conduct

The evidence from the post-settlement conduct, considered as a whole, demonstrates that Schering had little interest in Niacor-SR or any of the other licensed products. The lack of communication between Upsher and Schering about the development of Niacor-SR – especially during the fall of 1997, before Kos's disappointing sales were made public and after Upsher decided unilaterally to place only minimal effort into development activities – suggests that Upsher understood Schering was not particularly interested in the licensed products.¹⁰⁰ This conclusion is buttressed by the fact that Upsher simply ignored Schering's sporadic requests for information, and ultimately made a unilateral decision essentially to suspend its work, without eliciting even a mild protest from Schering. The post-settlement conduct only confirms the conclusion that Schering's payment of \$60 million was not consideration for the licenses.

E. Summary Factual Conclusions on the Valuation of the Upsher Licenses

There is a direct link between the payment by Schering for the Upsher licenses and Upsher's commitment not to enter before September 1, 2001. Schering's payments were neither keyed to any milestones in the development of the licensed products nor dependent on any obligations of Upsher to cooperate with Schering. At every negotiating session, Upsher's senior representative demanded compensation in return for an agreement not to enter. Some Schering representatives were concerned about the antitrust consequences of an outright payment to Upsher for delay, but Schering's senior management believed these obstacles

¹⁰⁰ Because the evidence shows that Schering had not shared the investment analysts' optimistic forecasts for Niaspan sales, the fact that Niaspan's sales were not as high as forecast fails to explain fully Schering's lackadaisical attitude.

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could be surmounted if the payments for the Upsher licenses were justified on a stand-alone basis.

As a practical matter, the only Upsher license that Schering attempted to value related to a niacin-based product, Niacor-SR. A number of people in Schering were familiar with niacin-based products, as the result of a recently terminated negotiation involving a different niacin-based product made by another company, Kos Pharmaceuticals. These people had serious reservations about the commercial potential of such products. For reasons that the parties have not explained, none of these knowledgeable people was included in the negotiations of the final price that ostensibly would be paid for a license to Niacor-SR – nor were these knowledgeable people consulted when a single Schering employee made the “forecast” of Niacor-SR’s sales and profit potential that was the basis for approval by the Schering Board.

This “forecast” was little more than a simple mathematical exercise. Even if we assume that there were serious time pressures, obvious questions were not even asked, nor were they pursued after the agreement was signed. It is not credible that Schering would have been satisfied with such a cursory examination, if management really was concerned about the value of the Upsher licenses. The post-settlement conduct of the parties reinforces these conclusions. The record demonstrates that Schering did not evidence any significant interest in the licensed products once the settlement had been concluded and, ultimately, all development was terminated. In the end, the Upsher licenses were worth nothing to Schering.

On the basis of the record as a whole, we find that there was a direct nexus between Schering’s payment and Upsher’s agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering’s evaluation of the Upsher licenses. We therefore conclude that Schering did in fact pay Upsher for delayed entry, which, in the circumstances of this case, was an agreement that unreasonably restrains commerce.

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V. The Agreement Between Schering and AHP

The complaint in this case also challenges the legality of a litigation settlement between Schering and AHP, which was concluded in June 1998 – approximately one year after the Schering/Upsher settlement. AHP agreed to a consent order based on this transaction, but Schering has continued to defend it, and the Initial Decision upheld Schering’s position. Complaint Counsel appeals from this dismissal as well.

There is far less record evidence about the Schering/AHP agreement than there is about the Schering/Upsher agreement, but our analysis will proceed along the same path, highlighting the similarities and the differences between the two agreements to the extent applicable. We will examine the core elements of Complaint Counsel’s case, consider whether it is necessary to address the merits of the underlying patent dispute and, finally, evaluate the ancillarity defense.¹⁰¹ Based on our analysis of the record, we reverse the Initial Decision and conclude that the Schering/AHP settlement was an unreasonable agreement in violation of Section 5 of the FTC Act.

¹⁰¹ There also was a side agreement in this settlement that provided for a payment of \$15 million by Schering to AHP’s ESI unit, in return for certain licenses. However, Schering has conceded that it agreed to pay another \$5 million (for “legal fees”) simply to induce AHP to settle the case, and it later agreed to pay \$10 million more contingent on FDA approval of *ESI’s generic version of K-Dur* – not the other products ESI licensed to Schering. (IDF 370-75; Schering Ans. Br. at 50.) FDA approval was obtained and the additional \$10 million were paid. The total payment was thus \$30 million. In these circumstances, we do not believe it is necessary to explore whether the ESI licenses were worth the \$15 million ascribed to them in the settlement.

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A. The Evidence in Support of Complaint Counsel's Case

The Schering/AHP agreement delayed entry of the generic product to be offered by the ESI subsidiary of AHP until January 1, 2004.¹⁰² We obviously have no evidence on the actual market impact of ESI's generic product, but we do have evidence of predicted effects similar to the predictive evidence available for Upsher's product. [redacted from public record version] [redacted from public record version]¹⁰³ In addition, the economic studies cited above found that generic prices fall further as the number of generic producers increases. See Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 83 (1997) ("expanded entry is consistent with a downward drift in the ratio of generic to brand-name price"); Richard E. Caves, *et al.*, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics 1, 34-38 (1991); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

The record does not contain similar predictions from the files of Schering, but we have no evidence from which we could conclude that the impact of ESI's generic would be qualitatively different from the impact of Upsher's generic. Since these predictions are consistent with the record evidence about both the predicted and the actual impact of another generic on the sales of *the same patented drug* (see Part II.B., above), we see no reason to arrive at a different conclusion on the likely competitive effects of an agreement that delayed ESI's entry.

¹⁰² The Commission's April 2002 settlement with AHP did not mandate an earlier entry date.

¹⁰³ [redacted from public record version]

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B. The Need to Address the Merits of the Underlying Patent Dispute

The patent dispute between Schering and AHP, like Schering's dispute with Upsher, involved issues of infringement as well as validity. Therefore, we cannot presume either that Schering had the right to exclude or that AHP had the right to enter. For the reasons set out in Part II.C., above, we believe it is neither necessary nor helpful to delve into the merits of the patent dispute.

C. The Ancillarity Defense

We have already weighed the evidence presented by Schering's expert witnesses on the general desirability of patent settlements and the possible efficiency justifications for payments by pioneers to generic manufacturers in some situations. We therefore believe it is appropriate to deal with this issue in the context of the Schering/AHP settlement in a way that parallels the conclusions about the Schering/Upsher settlement. As discussed above, it is possible to envision special hypothetical cases where some payments from pioneers to generics could be efficient and beneficial to consumers. An argument that these payments facilitate and are ancillary to procompetitive settlements invokes an affirmative defense, however, and a respondent who relies on it also has the burden of demonstrating that the facts fit some special hypothetical.

A sum that ultimately amounted to \$15 million was paid simply to get ESI's agreement on settlement terms that delayed generic entry until 2004. Of this amount, \$5 million were ostensibly for "legal fees." This might not be an unreasonable nuisance settlement – it is probably well in excess of AHP's attorneys fees, but obviously Schering faced litigation expenses of its own. However, the additional \$10 million, contingent on FDA approval of the generic product, are harder to justify. ESI was not a "cash starved" generic and there is no evidence that the payment would facilitate generic entry in force. Schering's claim is rather

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that ESI was adamant on the issue and that a settlement-minded judge put pressure on Schering to yield.¹⁰⁴

We accept that Schering was subject to intense, and perhaps unseemly, judicial pressure to settle the patent litigation, and Schering may well have been concerned about its future litigation prospects if it resisted. In other words, the pressure could have adversely affected its perceived bargaining position. We are troubled, however, by the fact that Schering's only response to the pressure was to look for innovative ways to structure payments to AHP; the January 1, 2004 date for generic entry was apparently non-negotiable. There is no record evidence to explain why the entry date was non-negotiable from Schering's point of view or why an earlier date would have been an unsatisfactory substitute for cash from AHP's point of view. In other words, there is no explanation for the failure to even explore an obviously less restrictive alternative. As discussed above in another context,¹⁰⁵ the mere fact that a patent holder's bargaining position has been impaired does not justify the payment of money to a potential generic entrant.

As a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence, and our decision on this aspect of the case will have no impact on the scope of the order we enter.¹⁰⁶ However,

¹⁰⁴ Schering Ans. Br. at 50.

¹⁰⁵ See discussion in Part II.B.4, above, rejecting an argument that payments are justified simply because Hatch-Waxman has shifted the relative bargaining power of the parties.

¹⁰⁶ The Commission's Order settling the complaint with AHP is final. See *Schering-Plough Corp.*, FTC Dkt. No. 9297, Consent Order as to American Home Products Corp. (Apr. 2, 2002), available at <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

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Commission determinations serve to provide prospective guidance as well as retrospective evaluations, and we believe it is important to signal our disapproval of the way that Schering responded to judicial pressures. Accordingly, we find that conduct of this kind violates the law.

VI. The Monopolization Counts

In addition to counts that invoke the conspiracy provisions of Section 1 of the Sherman Act (Comp. ¶¶ 68, 69), the complaint also pleads two counts that invoke the monopolization provisions of Sherman Act Section 2 (Comp. ¶¶ 70, 71).¹⁰⁷ As discussed above, there is adequate evidence to support the conclusion that the agreements to defer competition between Schering's patented drug and its generic equivalents will cause significant consumer harm, under Section 1 standards. The Upsher and AHP agreements postponed availability of substantial quantities of lower-priced therapeutically equivalent drugs and thereby caused consumer injury that is readily identifiable (even if it may not be readily quantifiable). In light of our conclusions on the conspiracy counts, it is not necessary to rule on the additional monopolization counts – and there are also affirmative reasons for declining to do so.

The proof in this case focused on the legality of two contracts, the Schering/Upsher and the Schering/AHP settlement agreements. There is no claim that unilateral conduct by anyone violated the antitrust laws. Moreover, determination of liability on the monopolization counts of the complaint would not affect our views on the appropriate order in this case. We therefore do not believe it would be useful either to canvass the record to see

¹⁰⁷ The counts plead a violation of Section 5 of the Federal Trade Commission Act, but the standards for applying Section 5 are, for the most part, co-extensive with the Sherman Act. *See* discussion in ABA Section of Antitrust Law, *Antitrust Law Developments* 607 (5th ed. 2002).

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whether there is adequate evidence to sustain these counts under the most commonly accepted standards for monopolization cases¹⁰⁸ or, alternatively, to consider whether the case should be remanded for further proceedings under the appropriate standards. Accordingly, we neither endorse nor reject the conclusions of the Initial Decision on these issues, but rather find that it is not appropriate for the Commission to address them at this time.

VII. The Appeal from the Administrative Law Judge's Evidentiary Rulings

Complaint Counsel have also asked the Commission to vacate four rulings by the Administrative Law Judge that excluded certain rebuttal evidence. If we were to do so, of course, it would be necessary to remand the case and reopen the record to admit the evidence.¹⁰⁹ For the reasons outlined below, we do not believe

¹⁰⁸ Reliance on direct evidence of market effects, rather than inferences from “market” shares, is a less familiar method of proof in a Section 2 monopolization context. *See id.* at 232 n.16 and cases cited (“Numerous cases have held specifically that proof of a relevant market is an essential element of any claim for monopolization or attempted monopolization under § 2.”); *but see PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107-08 (2d Cir. 2002); *Re/Max Int’l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999), *cert denied*, 535 U.S. 987 (2002).

¹⁰⁹ The courts and the Commission apply an “abuse of discretion” standard when reviewing claims of error in evidentiary rulings at the trial or initial hearing level. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 141 (1997), and cases cited therein; *Missouri Portland Cement Co.*, 77 F.T.C. 1643 (1970). While this standard means that the Commission will not routinely disturb the ALJ’s denial of discovery or exclusion of evidence, the Commission may reverse a procedural decision and reopen the record, as necessary or appropriate, where the ALJ’s ruling is found to be “unduly restrictive” or otherwise prejudicial or

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it is necessary to take this step at this time.

The first ruling denied discovery requested by Complaint Counsel, in order to rebut a claim that capacity constraints would have prevented Upsher from bringing its generic product to market before the agreed-on date of September 1, 2001. Since we find that Upsher's evidence on this point is insufficient, even without the rebuttal evidence, we decline to overturn the ruling on this issue.¹¹⁰

The second ruling excluded rebuttal testimony by witness Bresnahan on the substitutability of other potassium products for Schering's K-Dur 20. We have found that evidence of this kind is not material for a decision in this case, whatever relevance it might have for market definition in another kind of case. Accordingly, we decline to overturn the ruling.

The third ruling excluded certain rebuttal testimony by witness Max Bazerman on risk aversion because his underlying expert report was not filed in time. The excluded testimony apparently took issue with testimony of Schering's experts that Schering was

improper. *See, e.g., Foster-Milburn Co.*, 51 F.T.C. 369, 371 (1954) (hearing examiner improperly denied complaint counsel's request to present scientific rebuttal witnesses); *see also* Commission Rule 3.54, 16 C.F.R. § 3.54 (reserving the Commission's discretion to exercise all of the powers it could have exercised if it had made the initial decision and, if it believes it should have additional information or views of the parties bearing upon the order to be issued, to withhold final action pending the receipt of such information or views).

¹¹⁰ This does not mean that we agree with the ruling on the merits. If Complaint Counsel's chronological account is accurate, and if the evidence had been material, it seems that there could have been prejudice from a six-week delay in the resolution of the "emergency motion" in aid of discovery. *See* App. Br. at 78-81.

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risk averse in settlement negotiations with Upsher and AHP (and, hence, presumably willing to place a high value on settlement). We do not believe that the level of Schering's risk aversion is relevant to our decision in this case.

The extent to which parties are risk averse may affect how they are willing to compromise the entry date when settling patent litigation. However, we do not challenge agreements on entry dates, standing alone. The issue in this case is whether payments from pioneer to generic have distorted the calculus that would otherwise obtain – based on whatever risk preferences the parties might have – and our opinion does not depend on testimony about relative risk preferences. Accordingly, the ruling is harmless and will not be disturbed.¹¹¹

The fourth ruling excluded rebuttal testimony of a witness from Walgreens, again on the substitution of other products for K-Dur 20. The rejected testimony related to a market definition issue that is essentially the same as the issue involved in the second ruling, and we decline to overturn it for the same reasons.

We can revisit each of these rulings in the event that further proceedings in this case make it necessary to do so.

VIII. Conclusion

For all of the reasons outlined above, we conclude that both the Schering/Upsher and the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. Specifically, we reverse the Initial Decision and find that the charges in the complaint that are grounded in Section 1 of the Sherman Act (Paragraphs 68-69) have been proven. We neither affirm nor

¹¹¹ We again note, however, that the ruling could have been unduly prejudicial if Complaint Counsel's chronology is accurate and the evidence had been material for our decision. *See* App. Br. at 85-88.

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reverse the Initial Decision with respect to those charges in the complaint that are grounded in Section 2 of the Sherman Act (Paragraphs 70-71).

Although we find that these two settlement agreements violated Section 5, after an appropriately structured rule-of-reason inquiry, we also note that the agreements in question were consummated well before the Commission launched the investigations that resulted ultimately in complaints and consent orders in comparable situations.¹¹² Although counsel for Schering, at least, were aware of the particular problems posed by reverse payments and attempted (unsuccessfully) to avoid them, we do not believe that these problems were as obvious in 1997 and 1998 as they are today. Our own view of these matters has been informed by what we have learned about pioneer/generic settlements since that time. For these reasons, we have crafted an order that is appropriate in the circumstances.

The order provides for prospective relief only.¹¹³ We have found that the agreements were unreasonable restraints of trade because they were likely to cause consumer harm that outweighed any associated pro-consumer efficiencies. We also have found that the reverse payments did, in fact, cause delay and that this delay resulted in substantial consumer harm. We have not, however, attempted to quantify the net harm to consumers and express no opinion on what it might be.

¹¹² See cases cited in note 3, *supra*.

¹¹³ It may be appropriate in the future to seek retroactive relief, like disgorgement or redress, in comparable situations. See FTC Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820 (Aug. 4, 2003), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,231, *available at* <<http://www.ftc.gov/os/2003/07/disgorgementfrn.htm>>.

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The order is modeled on Complaint Counsel’s proposed remedy, with one significant exception. We delete in their entirety proposed provisions relating to a first-filing generic’s 180-day exclusivity. We have not analyzed the effects of any such agreements in this opinion and believe it is inappropriate to address them in the order.

Paragraph II of the order deals with final settlements of patent litigation. It prohibits settlements under which the generic “receives anything of value” and agrees to defer its own research and development, production or sales activities. Consistent with prior consent orders, there is a specific exception for payments to the generic that are linked to litigation costs, up to \$2 million, and for which the Commission has been notified of the settlement.

Paragraph III of the order prohibits settlement agreements that restrict the generic’s activities with respect to drug products that are subject to neither a pending claim of patent infringement nor a likely future claim. This provision is consistent with an extensive body of case law that prohibits restrictions on activities outside the scope of a patent claim.¹¹⁴

Paragraph IV of the order deals with interim settlements of pioneer/generic patent litigation. The substantive prohibition against providing “anything of value” to the generic is subject to a broad exception for agreements that are affirmatively sanctioned by a court order after notification to the Commission and full opportunity by the Commission to participate in the proceeding.

¹¹⁴ The basic reason is that, in the absence of a patent blockade, the arrangement “harms competition among actual or likely potential competitors . . .” U.S. Dep’t of Justice & Federal Trade Comm’n, Antitrust Guidelines for the Licensing of Intellectual Property (1995) § 3.1, *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, *available at* <<http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>>.

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Paragraph V of the order specifies the form of notifications to the Commission that may be required, and the remaining paragraphs provide for the usual compliance reports and visitation rights. The order expires in 10 years.

We finally would like to express our appreciation to all counsel for their extensive and thoughtful submissions that have helped us to resolve this complex matter.

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APPENDIX

Witnesses and People Referenced in Opinion

Sumanth Addanki, Economic Expert (Schering expert witness)

James Audibert, Schering-Plough, Senior Director of Commercial Optimization

Daniel Bell, Kos Pharmaceuticals, President and Chief Executive Officer

Timothy F. Bresnahan, Economic Expert (Complaint Counsel expert witness)

Nicholas Cannella, Upsher-Smith, Legal Counsel

Raul Cesan, Schering-Plough, President of Pharmaceuticals Worldwide

Toni DeMola, Schering-Plough, Member Cardiovascular Licensing Group

Michael Dey, ESI Lederle, Chief Executive Officer

Denise Dolan, Upsher-Smith, Marketing Official

Martin Driscoll, Schering-Plough, Vice-President of Sales and Marketing, Key Pharmaceuticals (Key marketed K-Dur 20)

James Egan, Searle, Formerly, Senior Director of Licensing and Business Development

Lori Freese, Upsher-Smith, Manager of Professional Services

James Furniss, European Pharmaceutical Expert (Schering Expert Witness)

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Karin Gast, Schering-Plough, Director of Business Development

Dean Goldberg, United Healthcare, Pharmaceutical Expert
(Complaint Counsel expert witness)

David Grewcock, Schering-Plough, Member Cardiovascular
Licensing Group

Marc Halvorsen, Upsher-Smith, Director of Clinical and
Regulatory Affairs

Andrew Hirschberg, Upsher-Smith, Consultant

John Hoffman, Schering-Plough, Associate General Counsel

Zola Horovitz, Pharmaceutical Expert (Schering expert witness)

Raman Kapur, Schering-Plough, President, Warrick
Pharmaceuticals (Schering-Plough's generic drug affiliate)

William Kerr, Economic Expert (Schering expert witness)

Paul Kralovec, Upsher-Smith, Chief Financial Officer

Thomas Lauda, Schering-Plough, Executive Vice President of
Global Marketing

Nelson Levy, Licensing Expert (Complaint Counsel expert
witness)

Vicki O'Neil, Upsher-Smith, Business Development Official

Mukesh Patel, Kos Pharmaceuticals, Licensing and Business
Development

Charles (Rick) Rule, Antitrust Expert (Upsher-Smith Witness)

Raymond Russo, Schering-Plough, Marketing Director, Key

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Pharmaceuticals

Russell Teagarden, Merck-Medco, Pharmaceutical Pricing Expert
(Complaint Counsel expert witness)

Paul Thompson, Schering-Plough, Licensing Attorney involved
with Upsher-Smith transaction

Ian Troup, Upsher-Smith, President and Chief Operating Officer

Jeffrey Wasserstein, Schering-Plough, Vice President of Business
Development

Robert Willig, Economic Expert (Schering expert witness)

Richard Zahn, Schering-Plough, Executive who supervised
Driscoll

Final Order

FINAL ORDER

The Commission has heard this matter on the appeal of Counsel Supporting the Complaint from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to reverse and vacate the Initial Decision and enter the following order. Accordingly,

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

- A. “Respondent Schering” means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Respondent Upsher” means Upsher-Smith Laboratories, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Upsher-Smith, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “180-day Exclusivity Period” means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(B)(iv) (2003)).

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- E. “AB-rated Generic Version” means an ANDA found by the Food and Drug Administration to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B) (2003).
- F. “Agreement” means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2003), or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2003).
- G. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).
- H. “ANDA Filer” means a party who has filed an ANDA with the FDA.
- I. “ANDA Product” means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.
- J. “Drug Product” means a finished dosage form (*e.g.*, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).
- K. “Effective Date” means the date of entering into the Agreement.
- L. “FDA” means the United States Food and Drug Administration.
- M. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b).
- N. “NDA Holder” means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With

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Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”) in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

- O. “Patent Infringement” means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.
- P. “Patent Infringement Claim” means any allegation made to an ANDA Filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA Product may infringe any patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.
- Q. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- R. “Reference Drug Product” means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.
- S. “Relinquish” means abandon, waive, or relinquish.
- T. “Sale of Drug Products” means the sale of Drug Products in or affecting commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44 (2003).

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II.

IT IS FURTHER ORDERED that in connection with the Sale of Drug Products, each Respondent shall cease and desist, directly or indirectly, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

- A. an ANDA Filer receives anything of value; and
- B. the ANDA Filer agrees not to research, develop, manufacture, market, or sell the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit a resolution or settlement of a Patent Infringement Claim in which:

- (1) a Respondent is either the NDA Holder or the ANDA Filer;
- (2) the value paid by the NDA Holder to the ANDA Filer as a part of the resolution or settlement of the Patent Infringement Claim includes no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or \$2 million; and
- (3) Respondent has notified the Commission, as described in Paragraph V.

III.

IT IS FURTHER ORDERED that, when a Respondent makes or is subject to a Patent Infringement Claim in which such Respondent is either the NDA Holder or the ANDA Filer, Respondent shall cease and desist, in connection with the Sale of

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Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

- A. could be approved for sale by the FDA pursuant to an ANDA; and
- B. is neither the subject of any written claim or allegation of Patent Infringement nor supported by a good faith opinion of counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement lawsuit in which it is either the NDA Holder or the alleged infringer ANDA Filer, such Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

- A. the parties do not agree to dismiss the litigation;
- B. the NDA Holder provides anything of value to the alleged infringer; and
- C. the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

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- (1) together with the stipulation for a preliminary injunction Respondent provides the court with the proposed Agreement, as well as a copy of the Commission's Complaint and Order in this matter;
- (2) Respondent has notified the Commission, as described in Paragraph V, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;
- (3) Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and
- (4)
 - (a) the court issues an order and the parties' agreement conforms to said order; or
 - (b) the Commission determines, at the request of Respondent, that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

PROVIDED FURTHER THAT nothing in Paragraph IV shall be interpreted to prohibit or restrict the right of Respondent unilaterally to seek relief from the court (including, but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)).

V.

IT IS FURTHER ORDERED that:

- A. Each Respondent shall notify the Commission, as required by Paragraphs II and IV, in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission at least thirty (30) days prior to

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consummating the proposed Agreement (hereinafter, the “First Waiting Period”) and containing the following information:

- (1) the docket number and caption name of this Order;
- (2) a statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;
- (3) identification of the parties involved in the proposed Agreement;
- (4) identification of all Drug Products involved in the proposed Agreement;
- (5) identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;
- (6) a copy of the proposed Agreement;
- (7) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and
- (8) all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the proposed Agreement.

B. If the Notification Letter is provided pursuant to:

- (1) Paragraph II, representatives of the Commission may make a written request for additional information or

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documentary material (as if the request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material.

- (2) Paragraph IV, Respondent may execute the proposed Agreement upon expiration of the First Waiting Period.

A Respondent may request early termination of the First Waiting Periods in this Paragraph V from the Director of the Commission's Bureau of Competition.

VI.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent intends to comply, is complying, and has complied with this Order. Each Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

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VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession or under their control relating to compliance with this Order; and
- B. To interview officers, directors, employees, agents, and other representatives of Respondents, who may have counsel present regarding such compliance issues.

IX.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which it becomes final.

By the Commission.

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in the agency by said Act, the Federal Trade Commission (“Commission”), having reason to believe that respondents Schering-Plough Corporation (“Schering”), Upsher-Smith Laboratories (“Upsher-Smith”), and American Home Products Corporation (“AHP”) have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

Nature of the Case

1. This action challenges unlawful agreements by Schering, Upsher-Smith, and AHP to delay the entry of low-cost generic competition to Schering’s highly profitable prescription drug K-Dur 20, a product used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.
2. When confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI Lederle, Incorporated (“ESI”), a division of AHP, Schering structured and entered into agreements with Upsher-Smith, AHP, and ESI that are keeping Upsher-Smith, ESI, and all other potential generic competitors out of the market. These agreements have cost consumers in excess of \$100 million.

The Respondents

3. Respondent Schering is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care

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products. Schering's net sales for 1999 were approximately \$9.2 billion.

4. Respondent Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development, and marketing of drugs. Upsher-Smith markets twelve brand-name products, all of which are sold in the United States.
5. Respondent AHP is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. AHP engages in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter medications. AHP had net sales of \$13.5 billion in 1999.
6. ESI Lederle, Incorporated, a division of AHP, engages in the research, manufacture, and sale primarily of generic drugs.
7. Schering, Upsher-Smith, and AHP, at all relevant times herein, have been, and are now, corporations as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
8. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Prescription Drugs

9. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States.
10. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. Such

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new drugs are referred to as “brand name drugs” or “branded drugs.” FDA approval for a branded drug is generally sought by filing a New Drug Application (“NDA”) with the FDA.

11. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the “Hatch-Waxman Act”), to facilitate entry of generic drugs while maintaining incentives for new drug development.
12. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application (“ANDA”) with the FDA. The ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references.
13. When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a “Paragraph IV Certification.”
14. The ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA. If, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period.
15. The Hatch-Waxman Act gives the first firm filing an ANDA for a generic version of a brand name drug with a Paragraph IV Certification a period of protection from competition from other generic versions of the drug. The FDA may not

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approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is referred to as “the 180-day Exclusivity Period.”

16. If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period.

The Impact of Generic Competition

17. Generic entry generally leads to a significant erosion of the branded drug’s market share and unit and dollar sales within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases even further and the branded drug’s market share erodes further.
18. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed.
19. Certain third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the use of generic drugs in lieu of their branded counterparts wherever possible.

Relevant Product and Geographic Market

20. The relevant geographic market in which to evaluate the conduct of Schering, Upsher-Smith, and AHP is the United States.
21. The relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including the

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manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

22. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain anti-hypertensive medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.
23. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.
24. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.
25. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.

Market Power

26. Schering has approximately 69% of the sales of potassium chloride supplements.
27. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.
28. At all times relevant herein, entry into the relevant markets was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, has not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders

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compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months.

29. At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.
30. At all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market power in the potassium chloride supplement market.

Background

31. Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand name drugs.
32. In 1998, sales of Schering's two K-Dur products were over \$220 million.
33. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.
34. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "743 patent"), which claims a controlled

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release potassium chloride tablet. The '743 patent expires on September 5, 2006.

35. The allegedly novel aspect of the '743 patent is the composition of the coating material applied to previously known potassium chloride crystals.
36. Schering anticipated generic entry prior to expiration of its '743 patent.
37. Prior to 1997, Schering projected that the first year of low-priced generic competition would reduce branded K-Dur 20's sales by over \$30 million.

Schering/Upsher-Smith Agreement Not To Compete

38. On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA filing.
39. Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor-Con M20 infringed Schering's '743 patent. This lawsuit triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product.
40. This lawsuit was strongly contested by Upsher-Smith.
41. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day Exclusivity Period.

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42. Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-Dur 20 until after the exclusivity period has expired, whether or not the other marketer has a product that infringes the Schering patent.
43. During the first half of 1997, Upsher-Smith prepared to launch commercially Klor Con M20 no later than May 1998, the month in which the 30-month stay of FDA approval was to expire.
44. On June 17, 1997, on the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the settlement, Schering agreed to make unconditional payments of \$60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products.
45. The \$60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering.
46. The licensed products were of little value to Schering. Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.
47. A court decision in the Schering patent infringement suit against Upsher-Smith would have removed barriers to generic competition, regardless of which party prevailed in the suit. If Upsher-Smith had prevailed, the FDA would have been permitted to grant final approval to Upsher-

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Smith's generic version of K-Dur 20, allowing Upsher-Smith to offer generic competition to Schering. After Upsher-Smith's 180-day Exclusivity Period had run, other potential generic competitors would have been eligible for final FDA approval. If Schering had prevailed, Upsher-Smith would not have been eligible for the 180-day Exclusivity Period. Since no other firm would have been eligible for the 180-day Exclusivity Period, there would have been no 180-day Exclusivity Period blocking final FDA approval of other generic competitors. Thus, the settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.

48. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.
49. Pursuant to its agreement with Schering, Upsher-Smith has not marketed Klor Con M20, nor has it attempted to develop another generic version of Schering's K-Dur 20.
50. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day Exclusivity Period has run.

Schering/AHP/ESI Agreement Not To Compete

51. On December 29, 1995, ESI submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA filing.
52. ESI planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day Exclusivity Period expired.

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53. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. Schering's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product.
54. By the end of January 1998, Schering, AHP, and ESI had reached an agreement in principle to settle their patent litigation.
55. Pursuant to their agreement in principle, Schering agreed to pay ESI up to \$30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. Schering agreed to pay ESI \$5 million up front; an additional \$10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another \$15 million for licenses of two generic products that ESI was developing. The payments for the licenses included \$5 million to be paid within ten days of execution of the agreement, plus \$10 million to be paid in annual installments over seven years.
56. Schering has made no sales to date of the two products it licensed from ESI.

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57. Instead of being based on the value of the licensed products, the \$15 million license payment is based on the amount that ESI wanted in order to settle its patent litigation with Schering.
58. On June 19, 1998, Schering and ESI executed their final settlement agreement. Their patent litigation had previously been dismissed with prejudice.
59. Schering has paid ESI over \$20 million and continues to make annual payments to ESI under the terms of their agreement.
60. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expires.

Other Potential Generic Competition

61. Andrx Corporation ("Andrx") filed an ANDA for a generic version of Schering's K-Dur 20 on June 2, 1999. Schering has not sued Andrx for infringement of the '743 patent.
62. Andrx cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run.

Effects Of Respondents' Conduct

63. The acts and practices of the respondents as herein alleged have had the purpose and effect to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of generic K-Dur 20 products into the relevant markets.
64. By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic

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versions of K-Dur 20. Absent those payments, neither Upsher-Smith nor ESI would have agreed to delay its entry for so long.

65. By making cash payments to Upsher-Smith and ESI, Schering protected itself from competition in the relevant markets from Upsher-Smith and ESI until 2001 and 2004, respectively.
66. Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith is entitled to 180 days of market exclusivity before any other generic competitor may enter with its own generic version of K-Dur 20. By avoiding a court decision that would have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.
67. As a result of respondents' conduct as herein alleged, consumers are being deprived of the benefits of competition from Upsher-Smith, ESI, or other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

First Violation Alleged

68. The agreement between Schering and Upsher-Smith that Upsher-Smith will not compete by marketing any generic version of Schering's K-Dur 20 until September 2001

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unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Second Violation Alleged

69. The agreement between Schering, AHP, and ESI that ESI will not compete by marketing any generic version of Schering's K-Dur 20 until January 2004, market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, or support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006, unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Third Violation Alleged

70. Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and engaged in conduct intended to unlawfully preserve such monopoly power in violation of Section 5 of the FTC Act.

Fourth Violation Alleged

71. Schering conspired separately with Upsher-Smith and AHP that Schering monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and all three respondents acted with specific intent and engaged in overt acts in furtherance of these conspiracies to monopolize the relevant markets, in violation of Section 5 of the FTC Act.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ)

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of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as

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early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on July 2, 2001, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate including, but not limited to, an order that requires the following:

1. Each respondent shall cease and desist from being a party to any settlement of patent infringement litigation which involves collateral restraints, such as a restraint on the research, development, manufacture, marketing, or sale of a "non-infringing" drug product – *i.e.*, a drug product not at issue in the patent infringement litigation.
2. Each respondent shall cease and desist from being a party to any agreement in which one party agrees to refrain from conducting or assisting a study of the bioequivalence or therapeutic equivalence of a product to the NDA holder's drug product.
3. Each respondent shall cease and desist from being a party to any agreement in which the NDA holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain from selling a drug product for any period of time.

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4. Schering shall immediately license for no compensation its '743 patent to Upsher-Smith and to ESI so as to allow the latter two companies to make, produce, and market commercially generic versions of Schering's K-Dur 20 and K-Dur 10. Said license must eliminate any and all legal claims that Schering would have for patent infringement by Upsher-Smith and ESI for selling the generic potassium chloride products for which each has already applied to the FDA for an ANDA.
5. Upsher-Smith shall immediately and without delay notify the FDA, in writing, that Upsher-Smith relinquishes its right to a 180-day Exclusivity Period for Klor Con M20 (its generic version of K-Dur 20).
6. Each respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such respondent's chief executive officer stating that it will abide by the terms of this order, to each of its employees who has the authority to enter into agreements concerning the research, development, manufacture, marketing, or sale of a drug product.
7. Each respondent shall take such other measures as are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices engaged in by respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of March, 2001, issues its complaint against said respondents.

By the Commission.

Initial Decision

INITIAL DECISION

By D. Michael Chappell, Administrative Law Judge

I. INTRODUCTION**A. Federal Trade Commission Complaint**

The Federal Trade Commission issued its Complaint in this matter on March 30, 2001. The Complaint charges that Respondents Schering-Plough Corporation (Schering), Upsher-Smith Laboratories, Inc. (Upsher-Smith), and American Home Products Corporation (AHP) engaged in conduct that violates Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Complaint alleges that Respondents entered into unlawful agreements to delay entry of low-cost generic competition to Schering's prescription drug K-Dur 20. Before detailing the findings of fact and conclusions of law, the following overview is provided.

Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 and K-Dur 10, both of which are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which expires on September 5, 2006. On August 6, 1995, Upsher-Smith filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith submitted a certification to the FDA, known as a Paragraph IV Certification, with this ANDA certifying that its product, Klor Con M20, did not infringe Schering's K-Dur 20 and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA.

Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor Con M20 infringed Schering's '743 patent. On June 17, 1997, Schering and Upsher-Smith agreed to settle their patent litigation. The

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Complaint alleges that through this settlement agreement, Schering agreed to make unconditional payments of \$ 60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products. Complaint at P44.

On December 29, 1995, ESI Lederle, Incorporated ("ESI"), a division of AHP, submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. The Complaint alleges that Schering and AHP reached an agreement in principle settling their litigation in January 1998, and they executed a final settlement agreement on June 19, 1998. Complaint at P54. AHP agreed that its ESI division would not market any generic version of Schering's K-Dur 20 until January 2004, would not market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, and would not support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006. Complaint at P55. AHP received a payment from Schering of \$ 5 million, and an additional payment of \$ 10 million when its generic product received FDA approval in 1999. Complaint at P55.

The Complaint alleges that the agreements between Schering and Upsher-Smith, and between Schering and AHP, were agreements not to compete that unreasonably restrained commerce in violation of Section 5 of the FTC Act. Complaint at PP68, 69.

The Complaint further alleges that Schering had monopoly power in the manufacture and sale of potassium chloride

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supplements approved by the FDA and narrower markets contained therein, and engaged in conduct intended to unlawfully preserve that monopoly power, in violation of Section 5 of the FTC Act. Complaint at P70. And, the Complaint alleges that Schering conspired separately with Upsher-Smith and with AHP to monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, in violation of Section 5 of the FTC Act. Complaint at P71.

B. Respondents' Answers

In answers filed April 23, 2001, Schering, Upsher-Smith and AHP denied that the agreements were unlawful, and offered a number of affirmative defenses. Upsher-Smith's answer asserted that its patent settlement agreement with Schering was lawful, reasonable, procompetitive and in the public interest.

In its answer, Schering asserted that its settlement agreement with Upsher-Smith allowed Upsher-Smith to bring its product to market in September 2001, five years before patent expiration. Schering asserted its settlement agreement with ESI was forged under active judicial supervision and allowed ESI to bring its potassium chloride product to market over two years before Schering's patent expired. Schering further asserted that the Complaint fails to acknowledge that Schering has a valid patent giving it a right to exclude infringing products, the Complaint fails to allege that the procompetitive efficiencies of the settlement do not outweigh any actual or potential anticompetitive effects, and that the relief sought by the Complaint is contrary to public policy because it interferes with settlement of patent infringement litigation.

C. Procedural History

On October 12, 2001, the Complaint against AHP was withdrawn from adjudication for the Commission to consider a proposed consent agreement. The Commission approved the final consent order on April 2, 2002. Although AHP is no longer a

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party to the case, the legality of the Schering/AHP agreement remains at issue with respect to Schering.

Trial commenced on January 23, 2002 and ended on March 28, 2002, covering 8629 pages of transcript, with 41 witnesses testifying, and thousands of exhibits admitted into evidence. Closing arguments were heard on May 1, 2002.

On February 12, 2002, Upsher-Smith moved to dismiss the Complaint due to Complaint Counsel's failure to establish a prima facie case. Pursuant to Commission Rule 3.22(e), the ruling on the motion to dismiss was deferred until all evidence was received. In a ruling from the bench on March 22, 2002, Upsher-Smith's motion was denied on the grounds that the evidence presented created factual issues of dispute sufficient to defeat the motion to dismiss.

On March 6, 2002, the parties filed a joint motion to extend the deadline for filing the initial decision. By Order dated March 14, 2002, extraordinary circumstances were found to exist sufficient to extend the deadline for filing the Initial Decision by 60 days until May 31, 2002. The record was closed on March 28, 2002. By Order dated May 29, 2002, continuing extraordinary circumstances were found to exist and the deadline was extended an additional 60 days. This initial decision is filed within 90 days of the close of the record.

D. Evidence

The Initial Decision is based on the transcript of the testimony, the exhibits properly admitted in evidence, and proposed findings of fact and conclusions of law and replies thereto filed by the parties. Numerous exhibits were conditionally admitted. Evidence, including transcripts from investigational hearings, which was conditionally admitted, was considered even though Complaint Counsel failed to properly connect up the evidence against all parties, and was found not to be dispositive to the determination of any material issue in the case.

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The parties submitted extensive post-trial briefs and reply briefs. The Initial Decision contains only the material issues of fact and law. Proposed findings of facts not included in the Initial Decision were rejected either because they were not supported by the evidence or because they were not dispositive to the determination of the allegations of the Complaint.

Many of the documents and testimony were received into the record in camera. Where an entire document was given in camera treatment, but the portion of the document relied upon in this Initial Decision does not rise to the level necessary for in camera treatment, such information is disclosed in the public version of this Initial Decision, pursuant to 16 C.F.R. § 3.45(a) (the ALJ may disclose such in camera material to the extent necessary for the proper disposition of the proceeding).

E. Summary

Based upon the theories advanced by Complaint Counsel, for Complaint Counsel to prove that the agreements to settle the patent litigation between Schering and Upsher-Smith and between Schering and ESI were anticompetitive requires a presumption that the '743 patent was not valid or that Upsher-Smith's and ESI's products did not infringe the '743 patent. There is no basis in law or fact to make that presumption. In addition, Complaint Counsel has failed to meet its burden of proving the relevant product market or that Schering maintained an illegal monopoly within that market. Despite the emotional appeal which may exist for Complaint Counsel's position, an initial decision must be based on substantial, reliable evidence and well reasoned legal analysis. For the reasons set forth below, the violations alleged in the Complaint have not been proven and the Complaint will be dismissed.

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II. FINDINGS OF FACT

A. Respondents

1. Schering-Plough Corporation

1. Schering-Plough Corporation ("Schering") is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. (Schering Answer at P3; CX 174 at FTC 0022249-50 (Schering 12/31/99 Form 10K)).

2. Key Pharmaceuticals, Inc. ("Key"), a Florida corporation, is a subsidiary of Schering. (CX 174 at FTC 0022315). It produces K-Dur 20, a 20 milliequivalent potassium chloride supplement, and holds the patent on that product. Schering Answer at P34. Warrick Pharmaceuticals Corporation ("Warrick"), a Delaware corporation, is a subsidiary of Schering. CX 174 at FTC 0022318. It produces generic pharmaceutical products, and in some situations, produces generic versions of Schering's patented products once another generic has entered the market. (Russo, Tr. 3429-30).

3. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (Schering Answer at P7).

4. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S. C. § 44. (Schering Answer at P8).

2. Upsher-Smith Laboratories, Inc.

5. Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a business corporation organized under the laws of the state of Minnesota that has issued shares of common stock. (CX 1

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(Upsher-Smith Articles of Incorporation); Upsher-Smith First Admissions, Nos. 1, 2. Its principal place of business is Plymouth, Minnesota. (Troup, Tr. 5397). Upsher-Smith is a privately-held company. (Troup, Tr.5398).

6. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Upsher-Smith manufactures pharmaceutical products at its facilities in Minnesota and ships products to the other 49 states of the United States. It purchases pharmaceutical ingredients for its pharmaceutical products from suppliers located outside Minnesota, and transfers funds across state lines in exchange for those ingredients. Upsher-Smith First Admissions, Nos. 12, 13, 14, 15, 16, 17, 18, 19, 20 and 21.

8. Upsher-Smith markets its products to retail, chain, and hospital pharmacies, and to key physician groups, primarily by means of wholesale and drug chain distribution channels throughout the United States. (CX 317 at USL 01643 (Upsher-Smith Financial Statements, 1/3/99 and 1/4/98)).

9. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. American Home Products Corporation

10. American Home Products Corporation ("AHP") is a corporation organized and existing under the laws of Delaware, with its principal place of business at Five Giralda Farms, Madison, New Jersey. It engages in the discovery, development and marketing of brand name and generic drugs, as well as "over the counter" medications. AHP Answer at P5; CX 484 at 05 00052.

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11. Wyeth-Ayerst Pharmaceuticals, Inc. ("Wyeth"), is a subsidiary of AHP. ESI Lederle, Inc. ("ESI"), is a business unit of Wyeth. ESI engages in research, manufacture and sale primarily of generic drugs. AHP Answer at P6.

12. On October 10, 2001, Complaint Counsel and counsel for AHP filed a Joint Motion to Withdraw Respondent American Home Products from Adjudication in order for the Commission to consider an executed proposed consent agreement. On October 12, 2001, the Commission issued an Order Withdrawing Matter from Adjudication as to Respondent American Home Products Corporation. The Commission approved the final consent order April 2, 2002.

B. The Pharmaceutical Industry

13. Newly developed prescription drugs are sometimes referred to as "pioneer" or "innovator" or "branded" drugs. (Hoffman, Tr. 2206-07; Dritisas, Tr. 4621). Approval for an innovator drug is sought by filing a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). (Hoffman, Tr. 2207).

14. Newly developed prescription drugs are often protected by patents. (Hoffman, Tr. 2215). A patent is granted by the federal government to the patent holder giving the holder exclusive rights to make, use, vend and to import the subject matter covered by the patent claims. (Miller, Tr. 3310-11:2; O'Shaughnessy, Tr. 7064-65).

15. A generic drug contains the same active ingredient as the branded or innovator drug, but not necessarily the same inactive ingredients. (Hoffman, Tr. 2207; Levy, Tr. 2186). Approval for a generic drug may be sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. (Hoffman, Tr. 2209; Troup, Tr. 5403). The ANDA applicant must demonstrate, among other things, that the generic drug is bioequivalent to the brand-name drug that it references. (Hoffman, Tr. 2208; Troup, Tr. 5403).

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16. When a brand-name prescription drug is protected by one or more patents, an ANDA applicant that intends to market its generic prescription product prior to the expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand-name drug or (2) the patents are invalid. (Hoffman, Tr. 2215-16; Troup, Tr. 5404). This is known as a "Paragraph IV Certification." (Hoffman, Tr. 2216; Troup, Tr. 5404).

17. A bioequivalent drug contains the same active ingredient as the reference drug and is absorbed into the bloodstream at the same rate and extent, and remains at certain levels for the same period of time as the reference drug. (Hoffman, Tr. 2208).

18. Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. (Hoffman, Tr. 2278).

19. Generic drugs can offer price competition to the branded drug. The generic enters the market at a lower price than that of the branded drug. (Teagarden, Tr. 210-11; Goldberg, Tr. 137-38; Dritsas, Tr. 4743, 4904-05).

20. The price of generic drugs falls even further as additional generic versions of the same branded drug enter the market. (Schering Answer at P17; Goldberg, Tr. 120-21; Rosenthal, Tr. 1543).

21. Sales of the branded product decrease after generic entry because generics are substituted for the branded product. (Rosenthal, Tr.1538; Bresnahan, Tr. 462-63).

22. In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. (Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at P18). A pharmacist cannot substitute a generic that is not AB-rated for a

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branded drug without the physician's approval. (Bresnahan, Tr. 491; Russo, Tr. 3468).

23. In some states, pharmacists are required to substitute an AB-rated generic unless the physician directs otherwise. (Bresnahan, Tr. 1178; Addanki, Tr. 5998).

24. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. (CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93).

C. Geographic Market

25. The geographic market is the United States. (F. 26-28).

26. Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose products have been approved for sale in the United States by the FDA. (Hoffman, Tr. at 2206).

27. Schering has FDA approval to sell its K-Dur extended release potassium chloride tablets. (Kerr, Tr. 6561). Schering sells K-Dur throughout the United States. (CX 18 at SP 23 00044). Of the \$ 290 million in K-Dur 20 sales in 2000, Schering made \$ 287 million of those sales in the U.S., and \$ 3 million worth internationally in 2000. (Audibert, Tr. 4212-13).

28. Upsher-Smith has FDA approval to sell its Klor-Con M extended release potassium chloride tablets. (CX 59; Hoffman, Tr. 2273-74). Since Upsher-Smith began Klor Con M20 in September 2001, Upsher-Smith has been shipping it to all the major wholesalers and chain distribution centers throughout the United States. (Kralovec, Tr. 5076-77). Upsher-Smith does not sell Klor-Con M20 outside of the United States. (Dritsas, Tr. 4620).

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D. Relevant Product Market

29. The relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. (F. 31-118).

30. Professor Bresnahan incorrectly defined the relevant product market as K-Dur 20 mEq. (F. 31-118).

1. K-Dur 20 is one of many potassium chloride products on the market

31. K-Dur is a potassium chloride product marketed by Schering. (Russo, Tr. 3410-11). K-Dur is primarily used to treat potassium depletion in coronary artery disease patients. (Russo, Tr. 3410-11). To treat a patient's coronary artery disease, physicians often prescribe products that are also diuretics, causing a depletion in potassium, referred to as hypokalemia. (Russo, Tr. 3410-11; Goldberg, Tr. 125-26).

32. K-Dur is marketed in 10 mEq and 20 mEq dosage strengths. (Russo, Tr. 3411). The 10 mEq and 20 mEq labels denote the amount of potassium within the tablet. (Russo, Tr. 3415).

33. There are at least 23 potassium supplements on the market. (Russo, Tr. 3414; SPX 2209-31; CX 17).

34. Reports from the IMS database reflect that the potassium chloride supplement category includes a number of products, including K-Dur 10 and 20, Micro K, Micro K 10, Slow K, K-Tab, Klor Con 8, Klor Con 10, Klor Con M10, Klor Con M20, as well as other general tablet/capsules and generic forms of potassium chloride. (USX 1010; Bresnahan, Tr. 889-90).

35. Managed health care offers many choices of oral potassium chloride supplements. There were at least 24 different combinations of brand and generic potassium chloride products

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listed on the 2001 United Healthcare Preferred Drug List. (Goldberg, Tr. 154; USX 277).

36. As of 2001, there were numerous branded and generic potassium chloride products on Merck-Medco's formulary. (Teagarden, Tr. 207, 216-17; CX 56; CX 57). A formulary is a list of drugs that the physicians keep on hand to determine what products and what portion of the cost the managed care organization will reimburse to the patient. Dritsas, Tr. 4648.

37. Medco, a pharmacy benefit manager and Merck-Medco's predecessor, regards 10 mEq and 20 mEq potassium chloride products to be "competing." (Teagarden, Tr. 226; USX 131 at Merck-Medco 000206).

2. Potassium chloride products are therapeutically equivalent

38. The demand for a potassium supplement "begins when a patient goes in to a physician and they're treated for hypokalemia, so the doctor would write a prescription for KCl." (Dritsas, Tr. 4644; Bresnahan, Tr. 696).

39. If a physician prescribes a specific amount of potassium, any potassium chloride product would be effective. (Freese, Tr. 4951-52). A prescription for 20 mEq of potassium could be satisfied with a potassium chloride powder, effervescent, or liquid. (Freese, Tr. 4953-54; USX 410 at 190301). Because potassium products are all therapeutically interchangeable, a pharmacist could dispense 20 mEq of potassium chloride in whatever product form is appropriate for the patient. (Freese, Tr. 4956).

40. At maintenance, a physician will typically prescribe approximately 40 mEq of potassium per day. (Russo, Tr. 3423). If a doctor writes a prescription for K-Dur 20, a patient will take two tablets (one tablet two times a day, with meals). (Russo, Tr. 3423-24). If a patient's prescription is written for a 10 mEq

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product, the patient will have to take four 10 mEq tablets, likely two in the morning and two in the evening. (Russo, Tr. 3424).

41. Just because a potassium chloride product is not AB-rated to K-Dur 20 does not mean that it is not therapeutically interchangeable for K-Dur 20. (Dritsas, Tr. 4689-90; CX 740).

42. The FDA's designation of a generic pharmaceutical as "AB-rated," rated or bioequivalent, to a pioneer drug does not necessarily define the product market for antitrust purposes. (Addanki, Tr. 5684). Professor Bresnahan incorrectly defined the relevant market as consisting of 20 mEq tablets and capsules; and a 20 mEq tablet is not bioequivalent to a 20 mEq capsule. (Addanki, Tr. 5684; Bresnahan, Tr. 675; CX 1586). An AB-rated generic is substitutable for the branded product, but that does not mean that the AB-rated generic is the only potential substitute for the branded product. (Addanki, Tr. 5684).

43. K-Dur 20's 20 mEq dosage does not give it a therapeutic advantage over other potassium chloride products. (Russo, Tr. 3421).

44. K-Dur 20 is therapeutically interchangeable with two Klor Con 10s. (Dritsas, Tr. 4655-56). There is no category of patients who can only take K-Dur 20 and not two Klor Con 10s. (Dritsas, Tr. 4661).

45. Two 10 mEq tablets would effectively release in a patient's stomach at approximately the same rate as one 20 mEq tablet. (Goldberg, Tr. 174-75). If a pharmacist were to give a patient two Klor Con 10 tablets, rather than a K-Dur 20, the patient would simply take the two Klor Con tablets at the time that he was supposed to take the one K-Dur 20 tablet. (Dritsas, Tr. 4660-61).

46. Upsher-Smith's 1996 marketing plan for its Klor-Con potassium products shows that the various release mechanisms for different potassium chloride products all delivered potassium, and therefore were therapeutically equivalent and comparable. (Dritsas, Tr. 4693-94; USX 1549; USL 13859).

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47. Dr. Addanki looked at whether there were side effect differences between different potassium chloride products that affected their substitutability for each other. (Addanki, Tr. 5693). The primary side effect associated with potassium chloride products is the possibility of gastrointestinal (GI) irritation. (Addanki, Tr. 5693-95). Gastrointestinal irritation is not a substantial problem, however, as its incidence is low for all oral potassium chloride supplements. (Addanki, Tr. 6163). K-Dur 20 does not eliminate this potential GI side effect. (Addanki, Tr. 5693-95). Thus, potential side effect issues do not affect the substitutability of other potassium chloride products for K-Dur 20. (Addanki, Tr. 5695).

48. Although Schering's marketing strategy for its K-Dur 20 product was to emphasize that it could increase patient compliance, there is no significant difference in patient compliance between K-Dur 20 and Klor Con 10. (Dritsas, Tr. 4662).

3. Customers viewed K-Dur 20 and other potassium chloride products as interchangeable

49. According to Complaint Counsel's witnesses, oral potassium chloride products are therapeutically equivalent.

50. Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. Goldberg, Tr. 126-27. Goldberg testified that most, if not all, potassium chloride products are therapeutically equivalent. Goldberg, Tr. 144 (discussing USX 277, United HealthCare's Preferred Drug List). Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. Goldberg, Tr. 144.

51. Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM") testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. Teagarden, Tr. 234 (discussing USX

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125); Tr. 240 (discussing USX 127). He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medeo did not even list K-Dur 20 as a proscription drug on its formulary. Teagarden Tr. 239-44. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmacutical companies. USX 127 at 176; USX 128 at 186.

52. Merck-Medco has consistently regarded potassium chloride products with different delivery systems as clinically equivalent and therefore interchangeable. (Teagarden, Tr. 249-50; (USX 123; USX 124; USX 125).

53. Merck-Medco equates microencapsulated tablets and capsules with wax matrix potassium chloride products. (Teagarden, Tr. 232, 247-48, 250; USX 123-25). Merck-Medco views branded and generic liquids, sustained release tablets and capsules, effervescent tablets, and powder potassium chloride supplements as alternative products substitutable for one another. (Teagarden, Tr. 233-34, 237-38, 240, 243, 255-56; USX 125; USX 127; USX 128; USX 126; USX 690). In addition, 8 mEq and 10 mEq products consistently are listed as substitutable alternatives on Merck-Medco's formularies. (Teagarden, Tr. 234, 240, 243-44, 256; USX 125; USX 127; USX 128; USX 690).

54. All the potassium chloride products on Merck-Medco's 2001 formulary are listed in the same therapeutical class. (Teagarden, Tr. 223-24; USX 131).

55. All the oral potassium chloride products on United Healthcare's Preferred Drug List are therapeutically equivalent. (Goldberg, Tr. 144-45).

56. Decision-makers at HMOs do not place a premium on K-Dur's delivery system or dosage form. (CX 13 at SP 003045; Addanki, Tr. 5691).

57. Physicians viewed K-Dur 20 as a product for which there were numerous other alternatives. (Dritsas, Tr. 4834). In 1995, 71

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percent of the prescriptions for potassium chloride supplementation were being written for products other than K-Dur 20. (Addanki, Tr. 6174; CX 13). As of August 1997, 6 out of 10 potassium chloride prescriptions were for something other than K-Dur 20. (Bresnahan, Tr. 1279).

58. A company could compete with K-Dur 20 simply by convincing a physician to change his prescribing habits. (Dritsas, Tr. 4690).

59. There was significant substitution back and forth between Klor Con 10 and K-Dur 20. (Dritsas, Tr. 4752; Addanki, Tr. 5702). Pharmacists were substituting two Klor Con 10s for one K-Dur 20. (Dritsas, Tr. 4834).

4. Schering viewed K-Dur 20 as competing in the same market as other potassium chloride products

60. Schering measures the sales performance of K-Dur 20 against the entire potassium chloride supplement market, including other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. (Russo, Tr. 3420; CX 18 at 23 000041; CX 17 at 003951, 003954; CX 20 at 00434). Schering's marketing plans indicate that there are over 20 different potassium chloride supplements, all competing in the same market. (Russo Tr. 3414-15; SPX 2209-2231; CX 17). Professor Bresnahan relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. (Bresnahan, Tr. 816). Bresnahan did not consider key portions of Schering's documents that show Schering considered K-Dur to be a part of a larger potassium chloride market. (Bresnahan 709-13, 721, 814-17, 824-25).

61. A 1996 Schering marketing backgrounder states that "K-Dur competes in a crowded \$ 264 million potassium market which continues to grow. . . ." (Russo, Tr. 3412; CX 17, CX 746; Bresnahan, Tr. 720-21).

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62. Schering's 1997 K-Dur Marketing Plan lists competing potassium chloride tablets and capsules. (SPX 977 at SP003849).

63. Schering perceived that K-Dur's major competitors were Klor Con and generic potassium chloride. (CX 20; Bresnahan, Tr. 827). A number of Schering documents characterize generic 10 mEq forms of potassium chloride as Schering's "major competitors." (Bresnahan, Tr. 1170).

5. Upsher-Smith viewed its potassium chloride products as competing in the same market as the other potassium chloride products

64. Upsher-Smith believed it was competing against everyone selling potassium chloride, including K-Tab, Micro-K, Ethex, K-Dur, and Slow K. (Addanki, Tr. 5711; SPX 1050). Upsher-Smith focused on the entire potassium chloride market and did not differentiate between dosage strengths. (Dritsas, Tr. 4692).

65. Upsher-Smith's documents indicate that it was looking at the entire potassium chloride market in positioning its Klor Con 10 potassium chloride product. (Dritsas, Tr. 4692; Addanki, Tr. 5711).

66. In its 1996 market share projections, Upsher-Smith assumed that the potassium market, which included K-Dur 10, K-Dur 20 and all other potassium products, was a \$ 218 million market. (Dritsas, Tr. 4700; USX 1549 at USL 13858).

67. A 1996 marketing plan for Klor Con tablets indicates that the major competitors to Klor Con 8 and 10 were K-Tab, Micro-K 10, Ethex and K-Dur 20. (Dritsas, Tr. 4691-92, 4696; USX 1549 at USL 13858).

68. An Upsher-Smith training manual, dated June 3, 1997, listed a variety of 10 mEq products competing in the potassium market, including Klor Con 10, K-Tab 10, Klotrix 10, Kaon-Cl, Apothecon's product Micro-K 10, ESI, Medeva, Ethex, K-Dur 10, K-Dur 20 and K-Plus 10. (Dritsas, Tr. 4738-39; USX 630 at USL

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15331). The manual listed a number of 8 mEq potassium products in the market, including Klor Con 8, Slow K, Copley 8, Warner Chilcott 8, Kaon-Cl 8, Abbott 8, Micro-K 8, and K-Plus 8. (Dritsas, Tr. 4739; USX 630 at USL 15332). Potassium powders in the market were Klor Con 20, Klor Con 25, K-Lor powder, Kay Ciel powder and Klor-vess powder 20. (Dritsas, Tr. 4739; USX 630 at USL 15333). K-Lor powder is marketed by Abbott Laboratories, a major, multi-billion dollar pharmaceutical company. (Dritsas, Tr. 4739-40). Finally, at least two effervescent tablet products were in the potassium market, Klor Con/EF and K-Lytc. (Dritsas, Tr. 4740; USX 630 at USL 15333).

69. Upsher-Smith's marketing documents reflect the fact that K-Dur 20 "competes directly against the 8 and 10 mEq strengths" of Upsher-Smith's Klor Con. (Bresnahan, Tr. 845; Dritsas, Tr. 4689, 4696; CX 740).

6. The substantial substitutability among potassium chloride products was reflected in actual competition between them

(a) Upsher-Smith directly targeted K-Dur 20 by emphasizing the substitutability of Upsher-Smith's Klor Con 10 mEq product

70. Upsher-Smith built demand for its Klor Con potassium chloride products based on therapeutic substitution. (Dritsas, Tr. 4653).

71. In order to compete against Schering's K-Dur 20, Upsher-Smith's sales representatives informed physicians and managed care organizations that they could more cheaply substitute two Klor Con 10 tablets for one K-Dur 20 tablet. (Dritsas, Tr. 4622-23).

72. In August 1999, Upsher-Smith employed a tactic to encourage high prescribers of K-Dur 20 to prescribe two 10 mEq tablets instead of one K-Dur 20. (Dritsas, Tr. 4765-66; USX 484 at USL 03330).

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73. K-Dur 20 tablets are scored, making them easier to break in half. (Freese, Tr. 4955). Because many patients had to break the large K-Dur 20 tablet in half to swallow it anyway, patients could save money by taking two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4622-23). Upsher-Smith's Klor Con 10 wax matrix tablet was about the same size as half a K-Dur 20 tablet. (Dritsas, Tr. 4624; Freese, Tr. 4955). Klor Con 10 was easier to swallow, though, because a halved K-Dur 20 tablet was bulky with rough edges. (Dritsas, Tr. 4624). Klor Con 10 was round and aqueous coated, a good alternative for patients complaining about swallowing a big tablet. (Dritsas, Tr. 4624).

74. Upsher-Smith implemented therapeutic switch incentive programs through its telephone sales force by targeting high volume K-Dur pharmacies, through visits to the headquarters of chains, wholesalers and managed care organizations, and by targeting long term care and select chains. (Dritsas, Tr. 4754-56; USX 1551 at USL 13795). Upsher-Smith also sent direct mail to high K-Dur prescribers about the cost savings of using two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4756-58; USX 1551 at USL 13795).

75. Direct mailings emphasized the quality of Klor Con and the 56 percent savings. (Dritsas, Tr. 4766; USX 484 at USL 03328). These mailings continued through November 1999. (Dritsas, Tr. 4766-67; USX 484 at USL 03331).

(b) Schering competed against other potassium chloride products

76. During the 1996-1997 period, Klor Con 10 sales increased 33 percent, moving from 12 percent of total prescriptions to 16 percent. (Bresnahan, Tr. 831). Generic potassium chloride sales increased during the same period, moving from 29 percent to 30 percent of total prescriptions by 1997. (Bresnahan, Tr. 832).

77. This growth was coming at K-Dur 20's expense. (CX 746 at SP 23 00039; Bresnahan, Tr. 743-45, 477; CX 18; SPX 901). Generic competition was growing at K-Dur 20's expense, in part

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because of the generics' price advantage, in part because of efforts to substitute two 10 mEq tablets for one K-Dur 20, and also because of managed care's role in requiring the use of generics. (Addanki, Tr. 5708, 5732-33; SPX 993 at SP 290039; CX 20 at SP 004040).

78. Schering expected that losses to 10 mEq generics would worsen over time. "As physicians change their prescribing habits and as the senior population moves into the managed care setting, the branded portion of the market will decrease and the potential for K-Dur volume growth will be limited." (CX 13 at SP 003046). Documents from the March 1995 time frame reflect concerns that staff HMO "decision makers do not place a premium on K-Dur's unique delivery system and dosage form." (CX 13 at SP 003047; Bresnahan, Tr. 717).

79. In 1995, Schering developed a marketing strategy to address competition from generic 10 mEq products. (CX 13 at SP 003046; Bresnahan, Tr. 715-16). Schering sought to develop brand awareness of, and brand allegiance to, the K-Dur brand to prevent an anticipated loss of market share to generic competition. (Bresnahan, Tr. 714-715; CX 13 at SP 003044-48).

80. As of July 1996, Schering was aggressively marketing K-Dur to gain sales from generic potassium chloride products. (CX 718 at SP 23 00039; Bresnahan, Tr. 742). Schering began a targeted mail series to promote K-Dur 20 in an effort to "blunt the continued growth of generic potassium usage." (CX 718 at SP 23 00054); Bresnahan, Tr. 758; CX 18 at SP 23 00039). Schering ran a significant number of promotional programs over a ten-year period that heavily promoted and marketed both its K-Dur products. (Russo, Tr. 3418-19).

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7. Brown Shoe factors not addressed in the preceding sections**a. No industry or public recognition of distinct markets**

81. Complaint Counsel's expert, Dr. Bresnahan, admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product that has unique features. (Bresnahan, Tr. 711-12; 1271-72).

82. No studies exist comparing patient compliance for K-Dur 20 and the Klor Con 8 mEq and 10 mEq wax matrix products. (Dritsas, Tr. 4662; Kerr, Tr. 6907-08).

83. IMS, the authoritative industry data source, lists a number of products and manufacturers under its single potassium supplement category numbered 60110. (Dritsas, Tr. 4709-12; 4800-01; USX 619 at 14884-996; USX 822 at 1-12). Schering's K-Dur 20 product is included in the IMS listing with all of the other potassium products. (Dritsas, Tr. 4709; USX 822 at 1). Professor Bresnahan concedes that "all economic researchers . . . working in this industry use" IMS data. (Bresnahan, Tr. 471). In fact, Bresnahan himself relied on IMS data for the graph in CX 1596. (Bresnahan, Tr. 735).

b. No peculiar characteristics and uses

84. There are no peculiar characteristics or uses for K-Dur 20. (F. 38-59).

c. No unique production facilities

85. The K-Dur 10 and K-Dur 20 mEq products are produced in the same Schering facility. (Bresnahan, Tr. 1272).

86. Upsher-Smith purchases from [ILLEGIBLE WORD], the same company that supplies the active ingredient for both the wax matrix Klor Con 8 and 10 and sustained release Klor Con M10 and M20. (CX 263 at 170356.).

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d. No distinct customers

87. There is no distinctive class of customers based on "demographics or other classification criteria" that prefer K-Dur 20. (Bresnahan, Tr. 707). K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-Lyte, Klotrix, Apothecon KCL and Ethex potassium chloride products are all prescribed for the same purpose of treating potassium deficiency. (Bresnahan, Tr. 1271; Dritsas, Tr. 4662).

88. There is no special group of patients that can only take K-Dur 20 and can not take other potassium products such as Klor Con. (Dritsas, Tr. 4661).

e. No distinct prices

89. In 1997, K-Dur had the same relative price as other potassium chloride supplements. (Teagarden, Tr. 224, 215, 218). During this time period, branded potassium products had "comparable" prices to K-Dur 20. (Bresnahan, Tr. 730). K-Dur and other potassium chloride supplements have "approximately the same" price. (Russo, Tr. 3426).

90. Dr. Bresnahan presented no statistical pricing study (Bresnahan, Tr. 1274), and did not even have pricing data for K-Dur 20, K-Dur 10, Klor Con 10 or for any other competitors (Bresnahan, Tr. 834-35, 867). During 1997, some potassium chloride products were more expensive than K-Dur 20. (Addanki, Tr. 5741-42; SPX 2069 at 1).

91. Dr. Bresnahan conceded that a pricing difference alone does not suffice to prove a separate product market. (Bresnahan, Tr. 1002). Prices of products that compete in a relevant market need not be close to one another because competition can occur in other dimensions. (Addanki, Tr. 6198).

92. Professor Bresnahan did not conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq

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sustained-release products and other potassium products. (Bresnahan, Tr. 689-90, 810).

93. Professor Bresnahan did not study the price trend of K-Dur 20 since September 1, 2001, when new entry occurred in the market. (Bresnahan, Tr. 1003).

94. Upsher-Smith launched Klor Con M10 on September 1, 2001. (Dritsas, Tr. 4827).

95. Upsher-Smith launched Klor Con M10 aggressively against K-Dur 10 simultaneously with the launch of Klor Con M20 against K-Dur 20. (Troup, Tr. 5486-88).

96. Just prior to the launch of Klor Con M10, K-Dur 10 sales began to fall dramatically beginning in the summer of 2001 and continuing through November 2001. (Dritsas, Tr. 4827; USX 1557). K-Dur 20 sales followed the same trend in the summer of 2001 and continued through November 2001. (Dritsas, Tr. 4823; USX 1586).

97. Upsher-Smith launched Klor Con M10 in the midst of K-Dur supply problems that began earlier in the summer of 2001, just prior to the launch of Klor Con M10. (Troup, Tr. 5488-89). Due to the lack of availability of K-Dur, Upsher's potassium chloride sales were already on the rise, when Klor Con M10 and M20 were launched into the market. (Troup, Tr. 5488-89).

98. Upon its entry into the market with Klor Con M10, Upsher-Smith had a significant sales increase in its potassium chloride products. (Troup, Tr. 5489-90). Upsher-Smith had record sales of wax-matrix potassium chloride products in the year 2001 as well. (Troup, Tr. 5490).

99. While Upsher-Smith enjoyed strong sales for its Klor Con M10 product, this was due partially to the supply shortages Schering faced for both K-Dur 20 and K-Dur 10, due to FDA compliance issues that arose during the summer of 2001. (Dritsas, Tr. 4682, 4825).

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100. Upon the launch of Klor Con M10 as a generic substitute to K-Dur 10, mandated state substitution for low cost generic alternatives took effect in several states. (Dritsas, Tr. 4824-25). These laws frequently block the prescribed branded product from being dispensed when a generic alternative is available, and thus prevent competition from the branded product completely. (Addanki, Tr. § 748-49; Dritsas, Tr. 4824-25). Similarly, in the K-Dur 20 market, state substitution laws that mandated substitution by a generic alternative negatively affected Schering's sales. (Dritsas, Tr. 4682, 4825).

101. K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. (CX 62 at SP 089326-27). K-Dur 10 sales performed just as Schering's K-Dur 20 performed. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. (CX 62-65).

102. Professor Bresnahan incorrectly asserts that K-Dur 20 is a monopoly (Bresnahan, Tr. 8147), but he concedes that K-Dur 10 was not a monopoly. (Bresnahan, Tr. 8146-47; Addanki, Tr. 5740).

103. While K-Dur 10 was not a monopoly product, K-Dur 10 sales fell just as dramatically as K-Dur 20, when Klor Con M10 became available on September 1, 2001. (Addanki, Tr. 5739-40; Dritsas, Tr. 4823-28; USX 1586; USX 1557).

f. Price sensitivity

104. Price is a major competitive factor in the potassium supplement market. (Dritsas, Tr. 4715-16; USX 626 at 15228).

105. Generic potassium products competed vigorously on price with branded potassium products, taking away sales and market share. (Dritsas, Tr. 4715-18, 4724-25, 4752-53, 4770-72; USX 626 at 15228; USX 1551 at 13791; USX 425 at 1002952).

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106. K-Dur 20 lost some market share to other potassium chloride products. (CX 18 at 23 00045, CX 20 at 004040; Dritsas, Tr. 4717-18, 4752-53). K-Dur 20 also took market share and sales from other potassium products. (Dritsas, Tr. 4719-20, 4724-25, 4742, 4752, 4841; CX 19 at 15228).

107. Generic manufacturers, such as Apothecan, increased their sales of potassium supplements with lower prices, suggesting price sensitivity and an ability to gain share at the expense of other products in the market with lower prices. (Dritsas, Tr. 4763-64, 4770-72, 4909-10; Addanki, Tr. 6176-79; CX 50 at 13474; USX 380 at 142328; USX 425 at 1002952.).

108. Upsher-Smith's Dolan wrote that a firm may have a gain in sales after cutting prices. Slow-K, for example, showed a unit increase of 41% from 1994 to 1995 while their dollar share continued to decline. (Addanki, Tr. 6181).

(i) Schering K-Dur prices were sensitive to other potassium supplement prices

109. According to Schering, the pricing of K-Dur 20 was depressed due to generic potassium competition. (Russo, Tr. 3416).

110. The 30% price difference between K-Dur 20 and the unbranded generic potassium products caused the sales of the generic products to rise, as noted in the 1998 K-DUR Marketing Plan. (CX 20 at 4040).

111. Schering's price for K-Dur 20 was not the highest for potassium chloride supplements during this time other products were both lower and higher than K-Dur 20 for a 20 mEq dose. (Addanki, Tr. 5741; SPX 2069). IMS data shows that in 1997, K-Tab 10 was the highest priced potassium chloride product. (Addanki, Tr. 5742; SPX 2069). Between 1996 and 2000, K-Dur 20 was never the highest priced potassium chloride supplement. (Addanki, Tr. 5743; SPX 2068). Schering's K-Dur 20 competed

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on price with other potassium chloride products by using discounts and rebate programs. (Addanki, Tr. 6172-73).

112. Professor Bresnahan testified that he did not compare Schering's prices against other potassium products' pricing in forming his opinion as to the relevant market in this litigation. (Bresnahan, Tr. 725, 867).

113. Professor Bresnahan also did not measure the cross-elasticity of demand between competing potassium products in conducting his analysis of the potassium market and K-Dur 20. (Bresnahan, Tr. 810).

(ii.) Schering paid large rebates

114. The annual rebates Schering-Plough paid to its customers for K-Dur for 1995 were \$ 21.005 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K-Dur for 1996 were \$ 28.659 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K-Dur for 1997 were \$ 17.593 million. The annual rebates Schering-Plough paid to its customers for K-Dur for 1998 were \$ 34.565 million. (CX 695 at SP 020699). The annual rebates Schering-Plough paid to its customers for K-Dur for 1999 were \$ 37.602 million. (CX 695 at SP 020700-701). The annual rebates Schering-Plough paid to its customers for K-Dur for 2000 were \$ 35.214 million. (CX 695 at SP 020701). These rebates were "significant" and were "more than 10 percent of the gross sales of K-Dur" in 2000. (Addanki, Tr. 6173-74). In the first six calendar months of 2001, Schering-Plough paid its K-Dur customers \$ 23.530 million in rebates for K-Dur. (CX 695 at SP 020702).

115. From October 1, 1997 to June 30, 2001, Schering-Plough paid its K-Dur customers a total of \$ 136.566 million in rebates related to its K-Dur product. (CX 695 at SP 020698-0702).

116. The rebates that Schering-Plough paid its K-Dur customers after the June 1997 Agreement with Upsher-Smith

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demonstrate that Schering-Plough "[was] competing on price through rebates" (Addanki, Tr. 6173). The tens of millions of dollars paid to K-Dur customers in rebates is inconsistent with the theory that Schering-Plough was a monopolist in the sale of its potassium products during this time period. (Addanki, Tr. 6173).

117. Professor Bresnahan did not study Schering's rebates at all in connection with his work in this case. (Bresnahan, Tr. 702). Nor did Professor Bresnahan study Upsher-Smith's rebate programs. (Bresnahan, Tr. 702). Further, Professor Bresnahan did not compare the two firms' relative level of rebate spending on potassium chloride (Bresnahan, Tr. 702).

g. No specialized vendors for various potassium products

118. No specialized vendors serve only K-Dur 20--both Klor Con and K-Dur 20 are dispensed by pharmacies in response to prescriptions written by doctors. (Bresnahan, Tr. 695-96). Both drugs are prescription medications for potassium. (Bresnahan, Tr. 696-97). Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. (Bresnahan, Tr. 696). Demand for both products begins when a patient presents himself to a doctor. (Bresnahan, Tr. 696). Prescriptions are dispensed for both products at pharmacies. (Bresnahan, Tr. 697-99).

E. The '743 Patent and Schering's K-Dur Products

119. Potassium chloride supplements are prescription drugs used to treat potassium deficiency (known as "hypokalemia"), a condition that often arises among individuals who take diuretic medications used to treat high blood pressure or congestive heart disease. (Goldberg, Tr. 125-26; CX 3 at FTC 190286-89; CX 19 at USL 15229). Potassium deficiency can cause muscle weakness and life-threatening cardiac conditions. (CX 3 at FTC 190286-88; CX 26 at USL 07336; Goldberg, Tr. 125-26; Schering's Answer at P22; Banker, Tr. 2950).

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120. Potassium chloride, the active ingredient in potassium chloride supplements, including K-Dur 20, is not patented. (Schering Answer at P33; Banker, Tr. 3251).

121. Patent number 4,863,743 ('743 patent) claims a "pharmaceutical dosage unit in tablet form for oral administration of potassium chloride" containing potassium chloride crystals coated with a material comprising ethylcellulose, having a viscosity greater than 40 [ILLEGIBLE WORD], and hydroxypropylcellulose or polyethylene glycol. (CX 12 at FTC 0021322). The novel feature claimed in the '743 patent is the particular coating applied to the potassium chloride crystals. The active ingredient, potassium chloride, was a known compound. The coating allows for sustained-release delivery of the potassium chloride. (CX 12 at FTC 0021319-20). Thus, the '743 patent relates primarily to the sustained-release formulation and does not cover the active ingredient itself. (Banker, Tr. 2947; Horvitz, Tr. 3625-27).

122. Key Pharmaceuticals, a division of Schering, owns the '743 patent. The '743 patent, issued on September 5, 1989, covers K-Dur 20 (as well as K-Dur 10, a 10 mEq version of the product) and expires on September 5, 2006. (Schering Answer at P34; CX 12 at FTC 0021318).

123. K-Dur 20 is a controlled release, microencapsulated, potassium chloride product developed by Key Pharmaceuticals in the 1980s and approved by the FDA in 1986. (Kerr, Tr. 7561). The "20" in K-Dur 20 refers to 20 mEq (milliequivalent), the amount of potassium contained in the 20 mEq dosage form. (Bresnahan, Tr. 489).

124. Complaint Counsel's expert witnesses did not reach an opinion as to whether the '743 patent is invalid or infringed by Upsher-Smith's or AHP's products. (Bresnahan, Tr. 670; Bazerman, Tr. 8568; Hoffman, Tr. 2351).

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F. Upsher-Smith's Potassium Products and Patent Litigation**1. Upsher-Smith's ANDA and the initiation of patent litigation**

125. On August 8, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor-Con M in two dosage forms, 10 mEq and 20 mEq, as bioequivalent versions of Schering's K-Dur products. (USX 695). Upsher-Smith subsequently amended its ANDA submission to remove the 10 mEq dosage form from consideration, due to the FDA's initial rejection of a biowaiver for the 10 mEq dosage form. (CX 255). The FDA determined that no ANDA filer was eligible to have exclusivity for any 10 mEq dosage form of any generic version of K-Dur. (USX 345).

126. At the time of its ANDA submission, Upsher-Smith was not aware that it was the first ANDA filing referencing K-Dur 20. (Troup, Tr. 5491; Dritsas, Tr. 4666). After amending its ANDA to remove the 10 mEq dosage form, Upsher-Smith submitted a Paragraph IV Certification. (CX 224). On November 3, 1995, Upsher-Smith notified Schering of its ANDA filing and Paragraph IV Certification with respect to the 20 mEq dosage form. (CX 224; Troup, Tr. 5404).

127. On December 15, 1995, pursuant to the time period set forth in the Hatch-Waxman Act, Schering sued Upsher-Smith for patent infringement in the U.S. District Court for the District of New Jersey, alleging that Upsher-Smith's Klor Con M infringed Schering's '743 patent. (USX 677; Kralovec, Tr. 5032; Troup, Tr. 5404). Trial of the patent case was scheduled to begin on June 18 or 19, 1997. (Hoffman, Tr. 3549).

128. No testimony or evidence was offered to show that Schering's filing of the patent litigation against Upsher-Smith was not initiated for the legitimate purpose of defending its patent.

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2. Settlement discussions between Schering and Upsher-Smith

129. In the patent litigation, Schering alleged that Upsher-Smith's Klor Con M20 product infringed the '743 patent because [redacted] (Banker, Tr. 5254-55; SPX 2258; SPX 2259). Schering also asserted that [redacted] [(Banker, Tr. 5257-59:16; SPX 2258; SPX 2260).

130. In its answer to Schering's complaint, dated January 29, 1996, Upsher-Smith denied that its product infringed "any claim of the '743 patent," and asserted, as affirmative defenses, that the claims of the '743 patent were invalid and that the '743 patent was unenforceable. (CX 226 at SP 08 00039-41). Upsher-Smith also filed a counterclaim for declaratory judgment that its product did not infringe the '743 patent and that the '743 patent was invalid and unenforceable. Upsher-Smith asserted that Schering brought its case with the intention of "trying to delay Upsher-Smith's FDA approval and thereby put off for as long as possible the time when it must face competition from Upsher-Smith's product." (CX 226 at SP 08 00041-42).

131. The patent infringement litigation between Upsher-Smith and Schering was vigorously contested from the outset. (Cannella, Tr. 3815; Kralovec, Tr. 5033; Troup, Tr. 5405-06). As the patent litigation continued through the spring of 1997, Mr. Ian Troup, Upsher-Smith's President and Chief Operating Officer, became increasingly concerned about the toll it was taking on Upsher-Smith. (Troup, Tr. 5405-06). The litigation was taking longer than Upsher-Smith had anticipated and was particularly rancorous. (Troup, Tr. 5405-07).

132. In April or May 1997, Troup first approached Schering about a possible settlement of the litigation. (Troup, Tr. 5397, 5408-09). The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation. (F. 129-62).

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133. The initial settlement meeting took place between Mr. Martin Driscoll, Vice President of Sales and Marketing for Key, and Troup at Schering's office in Kenilworth, NJ on May 21, 1997. (Troup, Tr. 5409). Troup stated that he wanted to obtain through settlement the earliest possible date to launch Klor Con M20 without incurring the damages that could arise from patent infringement. (Troup, Tr. 5411-12). Troup suggested to Driscoll that they settle the litigation by setting a date certain for Upsher-Smith to enter the market with its Klor Con M products sometime before September 2006, the expiration date of Schering's K-Dur patent. (Troup, Tr. 5410-11).

134. At this settlement meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher-Smith's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. (Troup, Tr. 5412). Troup stated that Upsher-Smith wanted to be on the market at an earlier date and that it would have problems with money and cash flow if its entry was delayed until 2005. (Troup, Tr. 5413).

135. The parties met again at Upsher-Smith's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Mr. Driscoll and Mr. Raman Kapur, President of Schering's Warrick subsidiary, attended these meetings on behalf of Schering. Mr. Troup and consultant Andrew Hirschberg attended on behalf of Upsher-Smith. (Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions. Nos. 7-9, 11-12; Upsher-Smith Second Admissions Nos. 9-10, 13-14, 22). At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher-Smith's products. (Troup, Tr. 5420).

136. During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. (CX 1511 at 18-19 (Kapur Dep.)). Troup stressed Upsher-Smith's need to replace its lost revenue from not having a generic K-Dur 20 product on the market. (Hoffman, Tr. 3568; CX 1511 at 18-19 (Kapur Dep.)).

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137. During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher-Smith's entry into the K-Dur 20 market. (CX 1511 at 22-23 (Kapur Dep)). The parties decided to approach settlement by splitting the remaining life on Schering's K-Dur patent. (Troup, Tr. 5424-26). Mr. Troup preferred an earlier date. (CX 1511 at 23-24 (Kapur Dep.)). Mr. Driscoll told Upsher-Smith that the earliest date he could offer for Upsher-Smith's entry was September 2001. (CX 1511 at 23 (Kapur Dep.)). Schering never suggested that it would consider an entry date earlier than September 1, 2001. (Troup, Tr. 5500).

138. At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture for Upsher-Smith research and development. (CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34). They also discussed the possibility that Schering might license one or more Upsher-Smith products, including cholestyramine, pentoxifylline and Upsher-Smith's sustained release niacin product, Niacor-SR. (CX 1511 at 14, CX 1495 at 62 (Kapur Dep.); SPX 1242 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34). Upsher-Smith described the expected clinical benefits of Niacor-SR, and Schering was aware of the market opportunity for Niacor-SR because it had been involved in evaluating the market for other, nearly identical projects. (CX 1495 at 70-71; SPX 1265 at 73 (Driscoll Dep.)). Troup was willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, as Upsher-Smith had no presence in Europe or elsewhere internationally. (Troup, Tr. 5432).

139. Prior to the parties' next face-to-face negotiation session, Mr. John Hoffman, Schering's General Counsel, spoke to, Mr. Nick Cannella, Upsher-Smith's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. (Cannella, Tr. 3824-25). Hoffman told Cannella that Schering viewed the upcoming meeting as an opportunity to discuss potential business opportunities between Schering and Upsher-Smith, not as an occasion to debate the merits of the

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underlying patent case. (Cannella, Tr. 3826; Hoffman, Tr. 3541). Hoffman stated that Schering "was not going to be paying Upsher-Smith to stay off the market." (Hoffman, Tr. 3541).

140. Prior to the parties' next face-to-face negotiation session, Troup and Hirschberg discussed what Upsher-Smith should ask for in exchange for a license to Niacor-SR. (Troup, Tr. 5448). Hirschberg recommended that Mr. Troup ask for \$ 100 million for a Niacor-SR license. (Troup, Tr. 5448).

141. Upsher-Smith representatives, Troup, Cannella and Hirschberg, and Schering representatives, Hoffman, Kapur, and Jeffrey Wasserstein, Vice President of Business Development, met in Kenilworth, N.J. on June 12, 1997. (Troup, Tr. 5436-38; Hoffman, Tr. 3539, 3541-42). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher-Smith's generic version of K-Dur. (Troup, Tr. 5439). Mr. Troup stated at the June 12 meeting that Upsher-Smith still had "cash needs" because all of the company's cash was tied up in two products in development, Upsher-Smith's generic version of K-Dur and its sustained release niacin product, Niacor-SR. (Hoffman, Tr. 3543).

142. Hoffman stated to Troup that the September 1, 2001 entry had already been negotiated, and that Schering wanted to discuss licensing opportunities. (CX 1509 at 49 (Hoffman Dep.); Troup, Tr. 5439-40). Mr. Hoffman told Mr. Troup that Schering would be "willing to do arm's length business deals that stand on their own two feet, and that's what we're here to discuss." (Hoffman, Tr. 3544).

143. Before the June 12, 1997 meeting Upsher-Smith required Schering to sign a confidentiality agreement regarding Upsher-Smith Niacor-SR product information. (CX 1041). Troup brought to the meeting a confidential printed presentation about Upsher-Smith's Niacor-SR product. (Troup, Tr. 5436-37; CX 1041). This presentation was similar to the presentations Upsher-Smith provided to Searle and the European companies interested in licensing Niacor-SR. (USX 538; CX 1023). Troup also provided

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Schering with two draft protocols for conducting post-market studies for Niacor-SR. (CX 714; CX 1043).

144. Troup confirmed that Upsher-Smith's offer of a Niacor-SR license extended only to non-NAFTA territories. (Hoffman, Tr. 3545; Troup, Tr. 5440-41). Schering was disappointed that Upsher-Smith would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. (Troup, Tr. 5443-44). Kapur also expressed his continued interest in Upsher-Smith's cholestyramine and pentoxifylline products. (Hoffman, Tr. 3545).

145. The parties discussed the market potential for Niacor-SR. (Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868). Upsher-Smith told Schering that latestage clinical work on Niacor-SR was finished and that Schering would be able to get on the European market with Niacor-SR soon. (Troup, Tr. 5441-43). Schering and Upsher-Smith discussed niacin combination therapy, the advantages of Niacor-SR versus immediate release niacin, the flushing side effects and Niacor-SR's effects on Lp(a). (Troup, Tr. 5583-87). Troup referred to Kos Pharmaceutical's niaspan product, and Kos's market capitalization, to show that Upsher-Smith's Niacor-SR niacin product had tremendous potential. (Troup, Tr. 5583-87; Cannella, Tr. 3829-30).

146. The June 12, 1997 meeting included a preliminary discussion concerning the price of the Niacor-SR product. Troup asked for \$ 70-80 million in his first offer to Schering. (Troup, Tr. 5449; Hoffman, Tr. 3545; SPX 1242 at 44-45 (Kapur Dep.); Cannella, Tr. 3830). Schering told Upsher-Smith it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher-Smith about its interest in pursuing a deal for Niacor-SR. (Hoffman, Tr. 3545-46; Cannella, Tr. 3832). The parties also discussed the potential licensing of other Upsher-Smith products, including Prevalite and Pentoxifylline. (Troup, Tr. 5445-46; Hoffman, Tr. 3544-45).

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147. Shortly before or after the June 12, 1997 meeting with Upsher-Smith in Kenilworth, Kapur and Driscoll briefed Mr. Raul Cesan, Schering's president of pharmaceuticals worldwide, on the Upsher-Smith negotiations. (CX 1510 at 66-67; SPX 1242 at 29-30 (Kapur Dep.)). Driscoll and Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher-Smith, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. (SPX 1242 at 30 (Kapur Dep.)). Cesan asked Kapur to contact Mr. Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. (SPX 1242 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.)).

148. Following Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin product, that the opportunity would cost Schering approximately \$ 60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth \$ 60 million to Schering. (Lauda, Tr. 4342-43). Kapur did not tell Lauda that this licensing opportunity was connected to patent litigation. (Lauda, Tr. 4344).

149. Lauda asked Mr. Jim Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform an assessment of Upsher-Smith's Niacor-SR product. (Lauda, Tr. 4344). Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert may have had. (Lauda, Tr. 4404). Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware that the Niacor opportunity had any connection to a patent suit. (Audibert, Tr. 4113).

150. Kapur sent Upsher-Smith's Niacor-SR data package to Audibert after receiving it from Troup. (CX 1511 at 40 (Kapur Dep.)). Audibert did not recall Lauda specifying a deadline for his review of Niacor-SR, but he knew from past experiences with

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similar requests that Lauda usually wanted the assessment to be completed quickly. (Audibert, Tr. 4112-13).

151. Audibert provided a formal written assessment of the commercial value of Niacor-SR, dated June 17, 1997. (SPX 2). Although Audibert did not complete his written assessment until June 17, 1997, Audibert and Lauda discussed Audibert's assessment before Audibert completed it. (Lauda, Tr. 4345; CX 1483 at 30 (Audibert I.H.)). In summary, Audibert concluded that Niacor-SR offers a \$ 100+ million sales opportunity for Schering. (SPX 2, at SP 1600045.) Annual dollar sales projections, in millions, were \$ 45 (1999), \$ 70 (2000), \$ 114 (2001), \$ 126 (2002). (SPX2, at SP 1600046-47). Detailed findings on Audibert's analysis and conclusions are set forth at F. 243-57.

152. The next meeting between Schering and Upsher-Smith took place on June 16, 1997, in Upsher-Smith's office in Plymouth, Minnesota. (Troup, Tr. 5452; Hoffman, Tr. 3550). Kapur, Hoffman, Wasserstein and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher-Smith. (Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834). Discussion at the June 16 meeting focused on the valuation of the package of Upsher-Smith products, including Niacor-SR and pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. (Troup, Tr. 5453). Over the course of the meeting, Upsher-Smith offered to license to Schering for the ex-NAFTA countries its wax matrix 8 and 10 mEq products and Klor Con M20. (Troup, Tr. 5453). Troup still wanted \$ 80 million and talked again about the fact that Kos' market capitalization was \$ 400 million based on the strength of Kos' similar niacin product, for which Kos had projected annual sales of \$ 250 million by the third year. (Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835). Schering made a counter-offer of \$ 60 million, which was accepted by Upsher-Smith. (Cannella, Tr. 3835; Troup, Tr. 5458).

153. The parties discussed, either at the June 16 meeting or shortly thereafter, that the \$ 60 million would be paid in installments. (Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511 at

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74-75 (Kapur Dep.)). To bridge the gap between Upsher-Smith's asking price and Schering's counter-offer, the parties negotiated milestone payments for launch of Niacor-SR in nine different countries throughout the world, including \$ 2 million for Japan and \$ 1 million each for eight other countries, totaling \$ 10 million in milestones. (CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59). Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to \$ 50 million and a 15% royalty on annual net sales in excess of \$ 50 million. (Troup, Tr. 5459; CX 347 at SP 12 00195).

3. Final negotiations and the June 17, 1997 Agreement

154. Following the June 16, 1997 meeting, the parties' first efforts to create a written agreement produced competing drafts. (Cannella, Tr. 3842-44). The final details of the agreement, including the amounts of the installment payments that would make up the \$ 60 million in up-front royalties, were worked out in a series of telephone calls between the parties over the next 24 hours. (CX 1511 at 74-76 (Kapur Dep.); Hoffman, Tr. 3548-50; Troup, Tr. 5459-60, 5464; Cannella, Tr. 3843-44).

155. After the conference calls to fine-tune the agreement, the agreement was memorialized in writing in an initial fax copy in the early hours of June 18, 1997. (Troup, Tr. 5464; Hoffman, Tr. 3549-50). The settlement agreement, CX 347, bears the date of June 17, 1997. (CX 347; Hoffman, Tr. 3550). However, it was actually signed at 2:00 or 3:00 a.m. on June 18, 1997. (Hoffman, Tr. 3550; Troup, Tr. 5467). Troup signed a fax copy on June 18 (Troup, Tr. 5467), and a hard copy of the final version on June 19, after returning to the office from a business trip. (Troup, Tr. 5465, 5467-68; CX 348).

156. The critical terms of the June 17, 1997 Agreement (CX 348) are set forth below:

IX. This Agreement constitutes a binding agreement between the Parties with respect to the subject matter

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set forth herein, conditioned solely upon the approval of the Board of Directors of Schering-Plough Corporation (the "Board"). This Agreement will be presented to the Board at its regularly scheduled meeting to occur on June 24, 1997.

X. Failure of any party to perform its obligations under the Agreement (except the obligation to make payments when properly due) shall not subject such party to any liability or place them in breach of any term or condition of the Agreement to the other party if such failure is due to any cause beyond the reasonable control of such non-performing party ("force majeure"), unless conclusive evidence to the contrary is provided. Causes of non-performance constituting force majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule material, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right. . . .

P3 Upsher-Smith agrees that it will not market in the United States its KLOR CON M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001. Effective as of September 2001, Upsher-Smith shall have a non-royalty bearing non-exclusive license under the '743 parent to make, have made, import, export, use, offer for sale and sell its, KLOR CON M 20 and KLOR CON M 10 potassium chloride tablets in the United States. . . .

P4 Each of Upsher-Smith and Schering shall stipulate to the dismissal without prejudice of the action known as Key Pharmaceuticals, Inc. v. Upsher-Smith

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Laboratories, Inc., U.S.D.C., D.N.J. (Civil Action No. 956281 (WHW)).

Paragraphs 7, 8, 9, and 10 grant Schering or its designated affiliates, the "SP Licensee," exclusive licenses for NIACOR-SR, KLOR CON 8, KLOR CON 10, KLOR CON M20, PREVALITE, and Pentoxifylline. For each of the drugs except PREVALITE, the territories of the exclusive licenses are all countries other than Canada, the United States, and Mexico. For PREVALITE, the territories are all countries other than Canada and Mexico (and in different packaging in the U.S.)

P11 In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, the SP Licensee shall make the following payments to Upsher-Smith:

- (i) An up-front royalty payment of twenty-eight million dollars (\$ 28,000,000) within forty-eight (48) hours of the date on which the Agreement is approved by the Schering-Plough Corporation's Board of Directors (the "Approval Date").
- (ii) An up-front royalty payment of twenty million dollars (\$ 20,000,000) on the first anniversary of the Approval Date.
- (iii) An up-front royalty payment of twelve million dollars (\$ 12,000,000) on the second anniversary of the Approval Date.
- (iv) Milestone payments due within ten (10) days of the first commercial sale of

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NIACOR-SR by the SP Licensee or its sublicensee in each of the following countries. . . .

P12 In the event that any court or governmental authority or agency rules that the licenses granted to the SP Licensee are void or invalid, then all such rights which are ruled to be invalid shall terminate and Upsher-Smith shall have the right, at its sole discretion, to purchase back, for nominal consideration, all such terminated rights. Any of Schering's payment obligations under the Detailed Agreement relating to such invalidated rights which have not become due and payable prior to the date of such ruling shall thereupon terminate.

157. The June 17, 1997 agreement achieved two purposes: (1) a settlement agreement of the patent infringement litigation whereby Schering agreed to grant Upsher-Smith a royalty-free license to enter the market with Klor Con M20 and Klor Con M10 on September 1, 2001 (five years before the expiration of Schering's patent on its K-Dur products) (Troup, Tr. 5461-63; Hoffman, Tr. 3548; CX 348); and (2) a license agreement for six separate products, and a related supply agreement for each of the six licensed products. (Troup, Tr. 5509, 5461-63; CX 348).

158. Paragraph 3 states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup, Tr. 5469-70). Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement.

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(Troup, Tr. 5470). No other restrictions on any of Upsher-Smith's other products were intended by the settlement agreement. (Troup, Tr. 5470; Cannella, Tr. 3849-50).

159. The license from Schering to Upsher-Smith for the '743 patent covers the marketing and sale of both Klor Con M20 and Klor Con M10 in the United States, even though Klor Con M10 was not a subject of the patent infringement lawsuit or a part of Upsher-Smith's ANDA filing. (Troup, Tr. 5470-72; Kerr, Tr. 6253-54; CX 348).

160. Paragraph 11 of the settlement agreement discusses royalty payments, which refers to the licenses for the six products: Niacor-SR, cholestyramine, Pentoxifylline, and the three potassium products. (Troup, Tr. 5473-74, 5631-33).

161. Paragraph 11 contains a reference that payment was in consideration of licenses, rights, and obligations described in paragraphs 1-10 of the entire agreement. (Troup, Tr. 5473-74; CX 348). The term "SP Licensee," by whom consideration was paid, only appears in Paragraphs 7 through 10 of the settlement agreement dealing with licenses, and not in Paragraphs 1 through 6, which involve only the settlement of the patent infringement litigation. (Troup, Tr. 5472-73, 5631-33).

162. No fact witness testified that the payments provided for in the June 17, 1997 agreement were not for Niacor-SR and the other products Schering licensed from Upsher-Smith.

4. Schering's Board of Directors approves the June 17, 1997 Agreement

163. The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. (Cannella, Tr. 3855-56; CX 347 at SP 12 00190). The presentation to Schering's Board sought authorization to enter into the license agreement with Upsher-Smith. (CX 338). It states that, during the course of Schering's discussions with Upsher-Smith, Upsher-Smith "indicated that a prerequisite of any deal would be to provide them with a

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guaranteed income stream for the next twenty four months to make up for the income that they had projected to earn from sales of Klor-Con had they been successful in their suit." (CX 338 at SP 12 00270). The Board was informed that Schering had made it clear to Upsher-Smith that any such deal would have "to stand on its own merit, independent of the settlement." (CX 338 at SP 12 00268). One Schering Board member testified that "it was made very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement." (SPX 1225 at 30 (Becherer Dep.)). Another Board member explained that "the licensing agreement that was being proposed would have to stand on its own merits," so that it "would be an agreement that would make sense in and of itself independent of anything else." (CX 1526 at 24-25 (Russo Dep.)).

164. The Board presentation provided sales projections for Niacor-SR of \$ 100 million plus in annual sales. (CX 338 at SP 12 00268). The presentation showed a net present value of \$ 225-265 million for the Niacor license. (CX 338 at SP 12 00275).

165. The Board presentation provided sales forecasts for sales of prevalite, pentoxifylline, and Klor-Con 8, 10 and M 20 "to be \$ 8 million a year in the first full year of launch, growing to \$ 12 million a year in the second full year, and then gradually declining in year four and thereafter. Net margins on the products are expected to be between 35% and 50%." (CX 338 at SP 12 00271).

166. A Board member testified that "the focus of this proposal was a licensing agreement for four products in a space that Schering was interested in for a \$ 60 million investment and a \$ 225 million plus economic value return. So, from the Board's standpoint, there was nothing about this that would cause any questions." (CX 1526 at 51 (Russo Dep.)). Based on the information presented to them and their understanding that the payments were for the licensed products, the Board approved the license deal. (CX 340 at SP 07 00003).

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5. The "any other sustained release microencapsulated potassium chloride tablet" clause was necessary and narrowly constructed to fully settle the litigation

167. Paragraph 3 of the settlement agreement states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added after some discussion between the parties so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup, Tr. 5469-70). Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement. (Troup, Tr. 5470).

168. A narrowly-constructed restriction like the one in the first sentence of paragraph 3 of the agreement is necessary in a patent settlement, as "it's essential to describe what it is that the parties can and can't do." (Kerr, Tr. 6334, 6336, 6338-39). In the pharmaceutical industry, settlement agreements necessitate narrowly-constructed clauses limiting the production of specific compounds, as generics need to be as similar as possible to the branded products and hence defy limitation by general language. (Kerr, Tr. 6338-39).

169. Professor Bresnahan has not identified any other product that was blocked by the language in the June 17, 1997 agreement that allegedly barred Upsher-Smith from marketing "any other sustained release microencapsulated potassium chloride tablet." (Bresnahan, Tr. 984). Nor is Professor Bresnahan aware that either Upsher-Smith or Schering had any product in mind other than the Klor Con M20 product when they drafted their agreement. (Bresnahan, Tr. 984).

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170. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were bottlenecked by the limiting clause in paragraph 3. (Dritsas Tr., 4836).

171. Professor Bresnahan conceded that "if the contract were otherwise procompetitive," it would be reasonable to read the language of the agreement as ruling out a "me-too product that is simply introduced under another name other than Klor Con M20 but is, in fact, Klor Con M20." (Bresnahan, Tr. 985). Such a provision would not be anticompetitive. (Bresnahan, Tr. 987-88, 990-91).

G. Whether the \$ 60 Million Dollars Was a Payment For Fair Value of Niacor-SR

172. Complaint Counsel's expert witness economist, Professor Timothy F. Bresnahan testified that a side deal at fair value did not raise competitive concerns. (Bresnahan, Tr. 932-33.) Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." (Bresnahan, Tr. 964-65. See also Tr. 660-61; 989-90.)

1. The market for cholesterol reducing drugs

173. In the mid-1990s, pharmaceutical companies were interested in the market for reducing cholesterol-reducing drugs. (Horovitz, Tr. 3623-60). The worldwide market for cholesterol lowering drugs had grown to become the seventh best selling drug class in the world. (SPX 235 at SP 16 00001). In 1997, the global market for cholesterol-reducing drugs was estimated at \$ 6-7 billion. (Kerr, Tr. 6871-72; SPX 225 at 3; Levy, Tr. 1763-64; Kerr, Tr. 6876). Forecasts in 1997 for the cholesterol-reducing drug market indicated that by the year 2000, the world market could total \$ 11 billion. (Kerr, Tr. 6875-76; SPX 225 at 3).

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174. Documents available to Schering in June 1997 showed that the market for cholesterol lowering drugs outside the U.S., Canada, and Mexico ("worldwide Ex-NAFTA") was larger than the U.S. market for cholesterol lowering drugs. (SPX 5 at SP 16 00447; CX 1042 at SP 16 00112). Complaint Counsel's pharmaceutical licensing expert, Dr. Nelson Levy estimated that in 1997, U.S. sales represented "roughly" half of worldwide sales of cholesterol lowering drugs. (Levy, Tr. 1914-15).

175. Although relatively inexpensive hyperlipidemic agents, including niacin, had been available for decades, annoying side effects interfered with patient compliance. (SPX 608 at SP 16 00344-345). In the late 1980's, however, the market for cholesterol lowering drugs began to take off with the widespread use of the newly developed and more expensive HMG-CoA reductase inhibitors, known as the statins. (SPX 608 at SP 16 00345). In the mid-1990's, there were five classes of cholesterol lowering drugs, including the statins that dominated the market, the fibrates, the bile acid sequestrants, niacin and probucol. (SPX 235 at SP 16 00001).

176. Niacin, or nicotinic acid, is a B vitamin that was first discovered to have hypolipidemic qualities in 1955. (SPX 608 at SP 16 00390). Niacin decreases LDL (known as "the bad cholesterol"), raises HDL (known as "the good cholesterol"), decreases triglycerides (TGs), and decreases lipoprotein(a) (Lp(a)). (SPX 608 at SP 16 00390-391; Horovitz, Tr. 3620; Audibert, Tr. 4099). Niacin has a unique profile in that it is the only drug shown to alter each of these lipids in the desired direction, and is one of the most effective compounds in increasing HDL. (Halvorsen, Tr. 3903; Horovitz, Tr. 3620; Levy, Tr. 1761; CX 1042 at SP 16 00072). Niacin's effectiveness in reducing total cholesterol, LDL cholesterol and triglycerides, as well as raising HDL cholesterol, has been demonstrated in numerous independent studies over the past 30 years. (USX 21 at 0077; USX 308 at 110462-64).

177. Niacin is also one of the only compounds known to decrease Lp(a). (SPX 608 at SP 16 00390-391; Halvorsen, Tr.

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3903; SPX 235 at SP 16 00002). Prior to 1997, several studies had associated Lp(a) with atherosclerosis and CAD, and treatment of Lp(a) was considered by European and U.S. experts to be one of the major unmet needs. (SPX 608 at SP 16 000362; SPX 235 at SP 16 00003; SPX 924 at SP 002780; CX 1042 at SP 16 00068-69).

178. In addition to its known efficacy profile when used as monotherapy, niacin had also been shown prior to 1997 to be an effective agent when used in combination with other cholesterol lowering drugs, such as statins. (SPX 608 at SP 16 00382, 391; Freese, Tr. 4962-64, 4989; SPX 52 at FTC 110463-110464; USX 141 at Moreton 00082; CX 1042 at SP 16 00074). As a result, physicians also prescribe niacin in combination with statins. (Horovitz, Tr. Tr. 3670; Brown, Tr. 3146-47; Freese, Tr. 4989).

179. Despite niacin's known profile as an effective cholesterol reducing agent, the immediate release formulations of the drug were not widely used prior to 1997 due to a side effect known as flushing. (Horovitz, Tr. 3620-21, 3625-26; USX 141 at Moreton 00082; SPX 924 at SP 002781; Audibert, Tr. 4100). Flushing is a result of increased blood flow near the skin, which causes redness, tingling and itching in almost all patients who use niacin. (Horovitz, Tr. 3625-26; Halvorsen, Tr. 3906; Brown, Tr. 3150). Although flushing does not present a safety risk, it is a nuisance side effect that significantly reduces patient compliance. (Halvorsen, Tr. 3906; Horovitz, Tr. 3620-21, 3625-26; Audibert, Tr. 4105). This flushing side effect prevented widespread use of what was recognized in the pharmaceutical industry as an otherwise effective cholesterol lowering agent. (Horovitz, Tr. 3620-21; Audibert, Tr. 4099-100).

2. Upsher-Smith's Niacor-SR and other products relevant to the settlement agreement

a. Development and testing of Niacor-SR

180. Upsher-Smith began the Niacor-SR (Sustained Release) development program in 1991. (Kralovec, Tr. 5010). Niacor-SR is

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a sustained-release formulation of niacin, meaning that it releases niacin gradually over a period of time. (Halvorsen, Tr. 3901; Horovitz, Tr. 3624). The purpose of sustained-release niacin is to eliminate flushing. (Halvorsen, Tr. 3905-06).

181. In 1997, both Upsher-Smith and another pharmaceutical company, Kos Pharmaceuticals, were each involved in the advanced stages of development for obtaining FDA approval of their own sustained-release niacin products. (Troup, Tr. 5474-75; USX 21 at 76-77). Upsher-Smith's Niacor-SR product presented an opportunity for Upsher-Smith to expand its sales in an extremely large market of cholesterol-reducing drugs. (Halvorsen, Tr. 3902-03).

182. By spring 1997, Upsher-Smith believed that it had completed all of the clinical development work on Niacor-SR, and was preparing to file its NDA for Niacor-SR. (Troup, Tr. 5474-75). As early as 1995, Upsher-Smith had conducted and completed the patient phase of two Phase III pivotal studies--the last phase of clinical development for gaining approval of a drug product by the FDA with over 900 patients. (Halvorsen, Tr. 3907). By July of 1996, the last of 300 patients had completed testing in two additional longer-term Phase III follow-on studies. (Halvorsen, Tr. 3911; CX 1019 at 175679). By June 1997, Upsher-Smith was in the process of developing and performing a short, 17-day, 38-healthy-volunteer pharmacokinetic study on Niacor-SR and was finalizing an individual and integrated study report so that Upsher-Smith could file its NDA. (Halvorsen, Tr. 3907).

183. As part of its Phase III testing for Niacor-SR, Upsher-Smith conducted two pivotal studies, as required by the PDA, the 920115 and 900221 studies. (Halvorsen, Tr. 3907-08). Upsher-Smith also conducted two longer term follow-on studies--the 920944 and 900837 studies. (Halvorsen, Tr. 3907-08). The last patient in the last of the four studies, the 920944 study, completed treatment in July 1996. (Halvorsen, Tr. 3909). The results of the Phase III studies available in June 1997 confirmed the safety and

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efficacy of Niacor-SR as a cholesterol-reducing drug. (Horovitz, Tr. 3641-42, 3658).

184. In addition to clinical safety and efficacy tests, the FDA requires a pharmacokinetic test ("PK test") for approval of an NDA submission. (Halvorsen, Tr. 3937). This test measures how a drug is absorbed and eliminated in the human body. (Halvorsen, Tr. 3936-37, 3939). The subject is dosed and then serial blood draws or urine samples are taken over time, for example hourly, with the purpose of plotting the concentration of the drug in the plasma or urine over time. (Halvorsen, Tr. 3936-37). In March 1997, the FDA ultimately agreed with Upsher-Smith that a multi-dose PK test was unnecessary for approval of the Niacor-SR NDA, and indicated that Upsher-Smith could seek approval based on a single-dose urine PK test. (Halvorsen, Tr. 3938-41; CX 917 at 107426-27; USX 281).

185. As of June 1997, Niacor-SR was Upsher-Smith's primary research project and was a highly valued asset. (Troup, Tr. 5474-75). By the second quarter of 1997, Upsher-Smith had spent \$ 13 million developing Niacor-SR--more than double all of Upsher-Smith's other projects combined. (Halvorsen, Tr. 3902; Dritsas, Tr. 4833).

186. In 1994, Upsher-Smith's market research showed a potential market for Niacor-SR of \$ 100 to \$ 400 million in 2000. (Kralovec, Tr. 5011-12). As of spring 1997, Upsher-Smith believed Niacor-SR had the potential to be a very successful product, with revenues of at least \$ 50 to \$ 100 million, and possibly as much as \$ 250 million. (Freese, Tr. 4978, 4990; Kralovec, Tr. 5011; Dritsas, Tr. 4829, 4831-32).

b. Upsher-Smith's comparison of Niacor-SR to Kos' Niaspan and cross-license agreement with Kos

187. In the mid-1990s, Kos Pharmaceuticals ("Kos") developed Niaspan, a sustained-release niacin product, which released niacin in a controlled dosage form for cholesterol therapy. (Patel, Tr. 7497; Halvorsen, Tr. 3945; Horovitz, Tr. 3640). Based on

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information available to Upsher-Smith in 1997, Niacor-SR and Niaspan were virtually the same in terms of efficacy and safety. (Halvorsen, Tr. 3947-48, 3960; Troup, Tr. 5524-25; Kerr, Tr. 6292; Horovitz, Tr. 3626, 3660; Lauda, Tr. 4351; Levy, Tr. 1315). During 1996 and 1997, Upsher-Smith's Director of Clinical and Regulatory Affairs, Dr. Mark Halvorsen continually kept track of the information on Niaspan that was publicly available. (Halvorsen, Tr. 3945-47; USX 535).

188. Comparing Kos's statements regarding Niaspan's performance on all of the lipid parameters--Lp(a), LDL, HDL, triglycerides--and Kos' statements regarding the safety profile of Niaspan to Niacor-SR's clinical and safety results, Dr. Halvorsen was confident in June 1997 that Niaspan and Niacor-SR were virtually identical. (Halvorsen, Tr. 3945-47; USX 535). Upsher-Smith executives believed Kos's Niaspan to be a direct and major competitor to Niacor-SR. (Kralovec, Tr. 5025; Halvorsen, Tr. 3946-47; Kerr, Tr. 6297).

189. By February 7, 1997, Kos and Upsher-Smith had negotiated and agreed on a cross-license under which [redacted] (Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9). [redacted] (Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9).

190. This agreement did not affect Upsher-Smith's ability to license its Niacor-SR product for sales outside of the United States. (Kralovec, Tr. 5027-28; Troup, Tr. 5479-80). In fact, the agreement explicitly allowed Upsher-Smith to license its extra-U.S. rights under the patent to third parties. (Troup, Tr. 5655-56; Kerr, Tr. 6462; CX 568 at 145288).

191. The financial market expected Kos' Niaspan product to be very successful. (Kerr, Tr. 6292-93; USX 1606). On April 21, 1997, investment firm Dillon Reed forecast that Niaspan sales would reach \$ 250 million by 2001--roughly the same amount that Upsher-Smith had estimated for its sales of Niacor-SR. (Kralovec, Tr. 5025-26; USX 535 at USL 11515; SPX 225 at 2). In May 1997, analysts at Dillon Reed estimated product revenues

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for Niaspan of \$ 17.3 million for 1998, growing to \$ 242.8 million in 2001. (Kerr, Tr. 6827-28; 6832-33; USX 239). Other investment reports at that time forecast Niaspan sales of \$ 20 million in 1997, growing to \$ 250 million in 2000. (Kerr, Tr. 6876-77; SPX 225).

192. The investment community's valuation of Kos Pharmaceuticals in the first half of 1997 bolstered Upsher-Smith's expectations for Niacor-SR. (Kralovec, Tr. 5025-26; Troup, Tr. 5441-43; USX 535).

c. Upsher-Smith's efforts to license Niacor-SR

193. In order to reach the maximum level of sales for Niacor-SR, Upsher-Smith believed that it would have to spend \$ 15 20 million to develop an effective sales force. (Kralovec, Tr. 5012-13).

194. Upsher-Smith saw great potential for Niacor-SR outside the U.S. market, but lacked a sales or marketing representative outside of North America. (USX 154-55; Freese, Tr. 4978; Kralovec, Tr. 5016; Troup, Tr. 5476; Halvorsen, Tr. 3970-71). By mid-1996, Upsher-Smith began actively looking for a Niacor-SR licensing partner for the European market. (Kralovec, Tr. 5028-29; Troup, Tr. 5476; Halvorsen, Tr. 3965). Upsher-Smith planned to market Niacor-SR in North America on its own and so did not discuss U.S. licensing of Niacor-SR with potential licensees. (Freese, Tr. 4977-78; Kralovec, Tr. 5016; Troup, Tr. 5431-33, 5440-41).

195. By the end of May 1997, Upsher-Smith's efforts to find a European partner for Niacor-SR had progressed to the point where Upsher-Smith representatives were holding face-to-face meetings with potential licensees to discuss licensing opportunities. (Freese, Tr. 4976-77; Halvorsen, Tr. 3965; Troup, Tr. 5475-76; Kralovec, Tr. 5020-21; USX 596-98; CX 880). These Upsher-Smith representatives reported to senior management that they were enthusiastic about finding a licensing partner. (Kralovec, Tr. 5020-21).

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196. In the first week of June 1997, Upsher-Smith executives were in Europe meeting with four potential licensing partners for Niacor-SR: Servier, Pierre Fabre, Esteve, and Lacer, (Halvorsen, Tr. 3871, 3967, 4026; Kralovec, Tr. 5028-29; Troup, Tr. 5476; Horovitz 3767; USX 596-98; CX 880). Upsher-Smith executives believed that potential European licensing partners were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. (Kralovec, Tr. 5017-18; 5020-21). As of June 1997, none of the four potential licensing partners for Niacor-SR had turned down Niacor-SR. (USX 596; USX 1523 at 58-59 (O'Neill Dep.); Kerr. Tr. 6321, 6818, 6815-16).

d. Other Upsher-Smith products relevant to the June 17, 1997 Agreement

197. In 1997, in addition to its niacin and potassium supplement families of products, Upsher-Smith had several other drugs on the market, or near market stage, including Pentoxifylline, Prevalite and Pacerone. (Dritsas, Tr. 4618-19, 4832-33; Troup, Tr. 5420-21, 5445). Although Upsher-Smith had plans for marketing these products in the United States, it lacked the presence and resources to market the drugs outside of North America. (Dritsas, Tr. 4636, 4833; Troup, Tr. 5431-32).

198. Prevalite, a bile acid sequestrant called cholestyramine, was another cholesterol fighting drug sold by Upsher-Smith. (Dritsas, Tr. 4618-19). Prevalite was a branded generic similar to Bristol-Myers Squibb's branded product Questran/Questran Light. (Dritsas, Tr. 4813-18; USX 591; USX 660). In 1996, Upsher-Smith had sales for Prevalite of \$ 7 million, with 1997 projected sales at \$ 8.8 million. (Dritsas, Tr. 4804-05, 4812-13; USX 591; USX 440; USX 627 at 15277).

199. Pentoxil, Upsher-Smith's trade name for Pentoxifylline, was another generic drug that was under development at Upsher-Smith in 1997. (Halvorsen, Tr. 3981). Pentoxifylline is used to treat peripheral intermittent claudication. Pentoxifylline allows red blood cells to be more flexible so that they may pass into blood vessels that have decreased in size and deliver oxygen.

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(Halvorsen, Tr. 3981). By June of 1997, Upsher-Smith had completed and submitted to the FDA all the clinical studies required for approval of its ANDA for Pentoxifylline as a generic form of the Trental brand of Pentoxifylline. (Halvorsen, Tr. 3981082). In 1997 alone, Trental sales were \$ 153 million. (Rosenthal, Tr. 1740). Trental's Pentoxifylline patent was set to expire in July 1997, and in June 1997, Upsher-Smith expected to be among the first generics approved to enter the market after the expiration of the patent. (Halvorsen, Tr. 3983). At that time, Upsher-Smith's internal market projections estimated that Upsher-Smith's Pentoxifylline would realize \$ 4.4 million sales in 1998. (USX 668 at 20666).

200. Pacerone, Upsher-Smith's trade name for an amiodarone product, was under development at Upsher-Smith in 1997. Pacerone is used to treat ventricular tachycardia, or rhythm management for the heart. (Dritsas, Tr. 4637-38, 4833). In June of 1997, Upsher-Smith believed that Pacerone was an important product and estimated first year sales of Pacerone would be \$ 10 million. (Troup, Tr. 5446).

3. Schering's interest in and valuation of Niacor-SR

a. Schering's interest in Kos' sustained release niacin product, Niaspan

i. Schering's negotiations with Kos

201. Kos filed an NDA for Niaspan with the FDA in May 1996. (SPX 18). Schering was interested in Niaspan in early 1997. Schering believed that a sustained release niacin product that solved flushing caused by immediate release niacins and did not elevate liver enzymes to the degree that some over-the-counter sustained release niacins had done could be commercially successful. (CX 1494 at 85; CX 1495 at 73 (Driscoll Dep.); SPX 1265 at 73 (Driscoll Dep.); Audibert, Tr. 4116-17).

202. Schering was interested in Niaspan not only as a late stage product that could generate revenues in the near term, but also

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because it presented an opportunity for Schering to enter the cholesterol lowering market in advance of its launch of ezetimibe, a drug that Schering was developing for the cholesterol market. (Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771).

203. In 1997, Mr. Raymond Russo was Key's marketing director for cardiovascular products in the United States. (Audibert, Tr. 4110; Russo, Tr. 3433-34). Russo participated in the negotiations with Kos regarding its Niaspan product. (Russo, Tr. 3449). James Audibert was Ray Russo's counterpart responsible for territories outside the United States and was for a time involved in the negotiations with Kos regarding Niaspan. (SPX 1224 at 77 (Audibert Dep.); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439).

204. By the time of Schering's discussions with Kos, the FDA had completed its medical review of Niaspan, and was discussing labeling with Kos. (Russo, Tr. 3445; CX 543; Audibert, 4102, 4105). The fact that the medical review had been completed meant that the FDA had judged the product to be safe and efficacious, and that it was just a matter of finalizing the actual labeling on the product before approval by the FDA. (Audibert, Tr. 4105-06).

205. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. (Russo, Tr. 3449). Under a co-promotion arrangement, the parties would split efforts in the field force and divide the cost of the marketing, (Russo, Tr. 3449). A co-promotion arrangement differs from a license, in which the company licensing the product would retain all control and all sales proceeds after royalties are paid. (Russo, Tr. 3449-50). Also, in a license arrangement, the licensee alone would be responsible for all the expenditures, investment and strategic direction associated with the product. (Russo, Tr. 3449).

206. Martin Driscoll, Schering's Vice President of Sales and Marketing for Schering's Key division, thought Kos' product

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labeling looked interesting. (CX 1495 at 96 (Driscoll Dep.); Driscoll, Tr. 1420, 2702). Schering asked Kos for more information, including Niaspan's clinical results supporting the labeling. (CX 1495 at 96 (Driscoll Dep.)). Kos was not forthcoming with additional information. (CX 1495 at 97-98 (Driscoll Dep.); SPX 1265 at 97-99 (Driscoll Dep)).

207. Kos wanted to maintain control over Niaspan's marketing and strategic positioning, while its partner gave Niaspan primary promotional positioning. (SPX 18). Kos wanted to have Niaspan promoted by Schering's sales representatives in the "primary position," meaning that it would be the first product a sales representative would discuss in a doctor's office. (Audibert, Tr. 4106). Schering explained that it could not guarantee that Niaspan would always be in the primary position because Schering had its own products, such as Claritin, that would be detailed first during particular seasons. (Audibert, Tr. 4107). Kos also wanted guarantees with respect to the level of call activity, asking for specific numbers of specific types of calls through the launch period. (Russo, Tr. 3451). Schering did not feel that it could accommodate the level of call activity that Kos wanted. (Russo, Tr. 3451). Schering would be more comfortable with secondary detailing. (Patel, Tr. 7555). Kos wanted "absolute maximum commitment from Schering in the form of first line details." (Patel, Tr. 7555). And, Kos also was demanding strategic control over the marketing and promotion of Niaspan. (Driscoll, Tr. 1423; Patel, Tr. 7557). Schering and Kos also discussed the issue of who would "book" sales. (Patel, Tr. 7556). Booking sales refers to which company records the sales that have been made. (Patel, Tr. 7556). Kos wanted to record, or "book," Niaspan's sales to show significant sales as a company. (Patel, Tr. 7556).

208. Audibert viewed Kos' demands as "unrealistic in terms of what their expectations were from us" regarding co-promotion activity. (Audibert, Tr. 2448). Audibert viewed Kos' demands for support from Schering's sales force as irrational, and very difficult for Schering to agree to. (Audibert, Tr. 4106).

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ii. Schering's evaluation, market research, and forecasts for Niaspan

209. On February 11, 1997, the information about Niaspan that Schering had been able to obtain from Kos was sent to Schering's cardiovascular licensing group, which includes Audibert. (Audibert, Tr. 4102; SPX 924). Audibert was asked to evaluate a Niaspan co-promotion deal, in which Schering would be promoting the product along with Kos, from the perspective of Global Marketing. (Audibert, Tr. 4100-01).

210. In his discussions with Kos and evaluation of Kos' materials. Audibert learned that it was possible to develop a sustained-release niacin product that was both safe and effective. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2452-53; SPX 18; SPX 21). For Audibert, Niaspan proved that the concept of a sustained release niacin that reduced flushing and solved liver toxicity issues could work. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2454, Tr. 4115-16). Kos told Schering that Niaspan had a very low incidence of elevated liver enzymes. (Audibert, Tr. 4105). Kos referenced a study by Dr. McKinney using a particular sustained release niacin on the market at that time. (SPX 18; Audibert, Tr. 4104).

211. Schering performed market research in the United States to determine doctors' interest in sustained release niacin. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). The market research included telephone interviews with ten prominent lipidologists who had attended Schering's recent meetings in New York concerning ezetimibe, another drug of Schering. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). Schering found that doctors would welcome a sustained release niacin product that reduced flushing and avoided liver toxicity issues, but would want more evidence that the product met those needs. (Russo, Tr. 3532; CX 576).

212. Schering was hopeful that Niaspan's delivery system would overcome the experts' reservations regarding sustained release niacin and flushing, liver toxicity and diminished efficacy.

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(Russo, Tr. 3503, 3509). Accordingly, Schering wanted to see the rest of the NDA filing for Niaspan for additional data that would support Kos' representations. (Russo, Tr. 3511). Schering also wanted to see the final labeling submitted to the FDA for Niaspan because Schering believed that if it showed no contraindications and a better side effect profile than other niacin products, Niaspan would be a very good product for Schering. (Russo, Tr. 3511-12).

213. Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. (Russo, Tr. 3455). Part of that process involved an assessment of the product's value to Schering and the preparation of sales forecasts. (Russo, Tr. 3455). Russo forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461 63, 3472); CX 550 at SP 002743; CX 551, at SP 002731). Under this scenario, Russo projected that Schering could achieve \$ 134 million in sales in 2002, rising thereafter to \$ 193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iii. Schering's offer to Kos for Niaspan

214. On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. (Russo, Tr. 3463-64; CX 554; SPX 619). Schering is the only company that gave Kos a written proposal before Niaspan was launched. (Patel, Tr. 7543).

215. [redacted] (Russo, Tr. 3589; CX 554). [redacted] (Russo, Tr. 3590; CX 554; Patel, Tr. 7666). [redacted] (Russo, Tr. 3590). [redacted] (Russo, Tr. 3589, 3590; CX 554; Patel, Tr. 7665; SPX 6190). [redacted] (Russo, Tr. 3589-90; CX 554). [redacted] (Russo, Tr. 3589, 3590; CX 554; Patel, Tr. 7665; SPX 619). [redacted] (Russo, Tr. 3589; CX 554; Patel, Tr. 7665; SPX 619). [redacted] Patel. Tr. 7666).

216. Schering's proposal did not contain up-front payments to Kos or equity investments. (Patel, Tr. 7605; CX 554).

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217. On May 21, 1997, one week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. (SPX 230; SPX 35; Patel, Tr. 7667). Kos did not react favorably to Schering's proposal. (Russo, Tr. 3465). Mr. Dan Bell, Chief Operating Officer of Kos, told Schering that its offer was practically "insulting," and that he was "offended" by it. (SPX 230; [Patel, Tr. 7669].

218. [redacted] (Patel, Tr. 7571). [redacted] (Patel, Tr. 7531-32, 7608; CX 556; CX 769). [redacted] (Russo, Tr. 3465-66). [redacted] (Russo, Tr. 3465). [redacted] (Russo, Tr. 3450). [redacted] (Bell, Tr. 7567; Patel, Tr. 7608-09; CX 556). [redacted] (Patel, Tr. 7567, 7607-08; CX 556)).

219. After receiving Kos' reaction to Schering's first proposal, Schering did not submit another proposal to Kos. (Russo, Tr. 3466, 3488; CX 558). Schering felt that Kos would be a difficult partner to deal with. (Audibert, Tr. 2450).

iv. Kos' discussions with other potential partners and subsequent sales of Niaspan

220. Kos' Niaspan entered the market in August 1997. (7 Tr. 1404 (Driscoll I.H.)). At the time of Niaspan's launch, Kos was still looking for a co-promotion partner for Niaspan in the U.S. (Patel, Tr. 7577).

221. In the fall of 1997, Kos had conversations with Searle Pharmaceuticals. (Patel, Tr. 7576; Egan, Tr. 7895-96; 7898). In early November, Searle met with Kos and the parties discussed Kos' demands for a U.S. co-promotion agreement. (CX 524). Kos demanded from Searle a large number of details for Niaspan. (Egan, Tr. 7986-88). Searle found Kos' demands unreasonable. (Egan, Tr. 7982). Kos wanted an up-front payment from Searle in the \$ 10-20 million range. (Egan, Tr. 7982). Kos also wanted a "ridiculous" and unreasonable percentage of the profits from any co-promote arrangement. (Hgan, Tr. 7984-85). Searle declined the Kos opportunity. (Egan, Tr. 7980).

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222. During the summer and fall of 1997, Kos was also pursuing discussions with SmithKline Beecham concerning a co-promotion arrangement for Niaspan. In August 1997, Kos discussed with Smith Kline the broad terms of a potential co-promotion partnership for Niaspan. (Patel, Tr. 7678; CX 508). As with Schering, Kos stated that it needed guaranteed detailing for Niaspan, that Kos wanted to book sales, and that Kos wanted the opportunity to co-promote a SmithKline product. (Patel, Tr. 7678-79; CX 508). SmithKline and Kos also discussed SmithKline's interest in non-U.S. rights to Niaspan. (CX 508). In November 1997, Kos announced disappointing sales results and its stock price dropped. (Patel, Tr. 7685, Tr. 7688); Levy, Tr. 2076-77). Subsequently, SmithKline and Kos did not to enter into an arrangement regarding Niaspan. (Patel, Tr. 7540).

223. Kos had other discussions with potential partners about a European license for Niaspan after November 1997. (Patel, Tr. 7589). [redacted] (Patel, Tr. 7615, 7587). Kos did not find a European partner for its Niaspan product. (Patel, Tr. 7540).

224. Overall, Kos' Niaspan has had a spotty history in the marketplace. (Kerr, Tr. 6329). Initially, Niaspan did not achieve nearly the expected sales levels predicted and Kos' stock price plummeted. (Kerr, Tr. 6329, 6331; USX 1607).

225. In 1998, Niaspan sales were poor. Sales for the first 6 months of 1998 totaled \$ 3.8 million and in August 1998, after being in the market one year, Niaspan's share of new prescriptions for the month was only 1.1% (Audibert, Tr. 4159; SPX 15). Total sales for 1998 were only \$ 15 million. (Driscoll, Tr. 1405). Two years after introduction, in 1999, Niaspan's sales were only \$ 37 million. (Kerr, Tr. 6331; USX 1613).

226. After four years, Niaspan is now moderately successful, with last year's sales equal to about \$ 100 million. (Kerr, Tr. 6331).

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b. Schering's Evaluation of Upsher-Smith's sustained release Niacin product, Niacor-SR

227. In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin product, that the opportunity would cost Schering approximately \$ 60 million, and asked if Global Marketing would perform an assessment of the product. (Lauda, Tr. 4342-43). Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide EX-NAFTA"). (Lauda, Tr. 4344).

228. Audibert began his review when he received the data package regarding Niacor-SR on June 12, 1997. (Audibert, Tr. 4113; Lauda, Tr. 4344). The package included results from the two phase III pivotal clinical trials conducted by Upsher-Smith to obtain registration of Niacor-SR, referred to by their protocol numbers 920115 and 900221. (Audibert, Tr. 4113-15, 4171; CX 1042; Halvorsen, Tr. 3907-08). The package also included information regarding two draft protocols for phase III-B studies Upsher-Smith was planning to conduct once the NDA was filed. (Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025). Phase III-B studies are studies conducted not as part of the initial registration of a product, but to support subsequent labeling revisions. (Audibert, Tr. 4114). One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. (Audibert, Tr. 4115; SPX 71-72).

i. Mr. Audibert's qualifications in June 1997**A. Expertise in Sustained Release Products and Cholesterol Lowering Pharmaceutical products**

229. James Audibert, who is currently employed within the Schering Plough Research Institute, was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. (Audibert, Tr. 4085, 4092). Audibert received his

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Bachelor of Science in Pharmacy from Northeastern University College of Pharmacy in 1974, and received his Master of Science in Pharmacology from Northeastern University College of Pharmacy in 1982. (Audibert, Tr. 4081). From 1976 to 1987, Mr. Audibert worked for two companies, both of which specialized in the use of sustained release technology to transform old compounds into new products. (Audibert, Tr. 4082-84).

230. In mid-1986, Schering acquired Key and, in March 1987, Audibert moved to New Jersey to work for Schering's marketing department. In April 1995, Audibert went to work in Schering's Global Marketing Department. (Audibert, Tr. 4085). In this position, Audibert was in charge of cardiovascular products, including cholesterol lowering products. (Audibert, Tr. 4092-93).

231. Audibert's responsibilities included working on a cholesterol-lowering agent Schering had in development called ezetimibe. (Audibert, Tr. 4093). By early-1997, Mr. Audibert began working with the research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. (Audibert, Tr. 4094). As part of this process, Audibert was also conducting a detailed evaluation of the market for cholesterol lowering drugs. (Audibert, Tr. 4094-95).

232. Audibert's detailed evaluation of the cholesterol lowering market included: (1) a review of secondary information and published literature regarding the market and products within the market; (2) conducting primary market research around the world, including interviewing physicians on what they perceived to be unmet needs and future trends in cholesterol management; (3) convening advisory panels to get input from experts in the cholesterol lowering area; (4) attending major cardiology meetings around the world dealing with current and future trends in cholesterol management, and the development of future cholesterol lowering products; and (5) traveling to subsidiaries around the world to meet with national experts and local opinion leaders in cholesterol management. (Audibert, Tr. 4095-96).

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233. As part of this process of evaluating the cholesterol lowering market, Audibert studied the profiles of the products that were already available for the treatment of cholesterol, as well as the anticipated profiles of future products, and evaluated what unmet needs existed within the market. (Audibert, Tr. 4097-98). This included studying the major cholesterol lowering products on the market in 1997, including the statins, the fibrates, the resins, and niacin. (Audibert, Tr. 4098). Audibert also conducted a detailed evaluation of the size of the cholesterol lowering market, which included: (1) examining the current size of the worldwide market by product and geographic territory; (2) predicting the future size of the cholesterol lowering market through conversations with opinions leaders, examination of cholesterol management treatment guidelines, estimation of the impact of future products on the market, and consideration of analyst reports published by the investment community. (Audibert, Tr. 4096-97).

234. [redacted] [(SPX 625 at SP 002914; SPX 25 at SP 002899)]. [redacted] [(SPX 625 at SP 002914; SPX 25 at SP 002899)].

235. [redacted] (Audibert, Tr. 4301-02; SPX 221 at SP 002895-2898). [redacted] (Audibert, Tr. 4302-04; SPX 231 at SP 002941-2942). [redacted] (Audibert, Tr. 4303; SPX 231 at SP 002944). [redacted] (Audibert, Tr. 4304; SPX 231 at SP 002944)].

236. [redacted] (Audibert, Tr. 4304).

237. Audibert also learned about niacin through his work on ezetimibe. (Audibert, Tr. 4098-99). Audibert was fully aware of the available scientific knowledge regarding niacin, including; the fact that niacin had been known for many years to have a positive effect on various lipid parameters that are important in cholesterol management, including lowering LDL, raising HDL, lowering triglycerides, and lowering Lp(a); the fact that niacin has been shown to be effective in long term morbidity studies; and the fact that niacin was incorporated into the NCEP treatment guidelines

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which recommend niacin as one of the agents for use in managing cholesterol. (Audibert, Tr. 4098-99). However, Audibert was also acutely aware of the fact that immediate release forms of niacin were limited by the side effect of flushing, and that sustained release niacin dietary supplements had been associated with substantial elevations in liver enzyme levels. (Audibert, Tr. 4100).

B. Involvement in the evaluation of Kos' Sustained Release Niacin Product in Spring 1997

238. On February 11, 1997, the information about Niaspan that Schering had obtained from Kos was sent to Schering's cardiovascular licensing group. (Audibert, Tr. 4102; SPX 924).

239. On March 13, 1997, Audibert and Russo initiated a conference call with Kos to discuss Niaspan. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). During this conversation, Audibert initiated a discussion of Niaspan's side effect profile, including in particular, the success of its sustained release formulation in: overcoming the flushing side effect of immediate release niacin, without causing the significant elevations in liver enzymes reported with over-the-counter sustained release niacin formulations. (Audibert, Tr. 4103-05; SPX 18 at SP 002776; Russo, Tr. 3443-44).

240. Kos advised Audibert that the rate of discontinuation due to flushing had been reduced to about 5% of patients. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). When Audibert raised the issue of liver enzyme elevations, Kos advised Audibert that, in contrast to the McKinney study in which 50% of patients experienced liver enzyme elevations above five times the upper limit of normal, only about 1% of patients in clinical trials with Niaspan experienced elevations of three times the upper limit of normal. (Audibert, Tr. 4103-05; SPX 18 at SP 002776).

241. Kos advised Audibert that it had filed an application for regulatory approval with the United States FDA, and that the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. (Audibert, Tr. 4105; SPX 18 at SP

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002776). Because the FDA does not proceed to a discussion of labeling until it has determined a product is safe and effective, the fact that the FDA had completed its medical review and was discussing labeling for Niaspan indicated to Audibert that the FDA had concluded that Niaspan's sustained release formulation was indeed safe and effective. (Audibert, Tr. 4101-02, 4105-06).

242. In late-March or early-April 1997, Audibert stopped participating as the international contact in the negotiations with Kos. (Audibert, Tr. 4111-12). Kos had indicated that it was focused on co-promotion of the product in the United States and that promoting Niaspan outside the United States was not a priority. (Audibert, Tr. 4106). Audibert terminated his involvement, in part, because he believed Kos' demands were "totally irrational" and he felt that it was unlikely that the parties would reach an agreement. (Audibert, Tr. 4111-12).

ii. Mr. Audibert's evaluation of the Niacor-SR opportunity in June 1997

A. Evaluation of market opportunity and product profile

243. Audibert conducted an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity. (Audibert, Tr. 4112). The 52-page data package provided by Upsher-Smith to Schering contained detailed summaries of the results of Niacor-SR's phase III pivotal trials, including all the information that Audibert required to conduct his evaluation of Niacor-SR's clinical profile. (Audibert, Tr. 4113-14).

244. The clinical data from Upsher-Smith's pivotal trials confirmed to Audibert that Niacor-SR was effective, and that it exceeded the regulatory hurdle of an average 15% reduction in LDL cholesterol. (Audibert, Tr. 4123; CX 1042; CX 1484 at 119-21 (Audibert Dep.)).

245. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR had significantly reduced

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the incidence of flushing as compared to immediate release niacin. (Audibert, Tr. 4117-19; CX 1042 at SP 16 00088-00089). As compared to immediate release niacin, Niacor-SR reduced the number of flushing occurrences more than four-fold. (Audibert, Tr. 4118-19; CX 1042 at SP 16 00089; Horovitz, Tr. 3645-46).

246. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR caused a very low incidence of liver enzyme elevations. (Audibert, Tr. 4119-20). Audibert concluded that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that seen with cholesterol lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained release niacin products. (Audibert, Tr. 4104-05, 4121, 4124; Horovitz, Tr. 3650-51). In his written commercial assessment, Audibert reported that the fact that some patients experienced liver enzyme elevations with Niacor-SR was consistent with the known side effect profile of the statins. (SPX 2 at SP 16 00044). Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. (Audibert, Tr. 4121-22; CX 1042 at SP 16 00093; Horovitz, Tr. 3649-50).

247. Based on his evaluation of the results of the pivotal trials, Audibert concluded that Niacor-SR was a safe and effective drug that satisfied the unmet need in the cholesterol lowering market that he identified in June 1997. (11 Tr. 4123-24 (Audibert Dep.)). Audibert had seen Kos' Niaspan as the "proof of concept," and he concluded based on the results of Upsher Smith's clinical trials that Upsher-Smith had also used sustained release technology to develop a safe and effective niacin product. (11 Tr. 2453-54 (Audibert Dep.); [Lauda, Tr. 4512-13].).

B. Mr. Audibert's Commercial Assessment of the Niacor-SR Opportunity

248. Having determined that Niacor-SR's product profile satisfied an unmet need in the marketplace, Audibert constructed

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a forecast of sales based on that product profile in that market. (Audibert, Tr. 4124). The process for constructing this sales forecast included: (1) an evaluation of the current and future size of the cholesterol lowering market; (2) an evaluation of how Niacor-SR would be positioned within that market; (3) an evaluation of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. (Audibert, Tr. 4124-27).

249. First, Audibert evaluated the current size of the market and made a projection of the future growth of that market for a period of ten years. (Audibert, Tr. 4124-25). Mr. Audibert used IMS data representing the current size of the cholesterol lowering market worldwide, excluding the U.S., Canada and Mexico ("worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. (SPX 5). The IMS data indicated that the size of the cholesterol lowering market in those territories in 1996 was \$ 4 billion. (SPX 5). Mr. Audibert's handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. (SPX 5). Audibert estimated an average annual growth 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. (SPX 2 at SP 16 000046). Second, Audibert evaluated how Niacor-SR would be positioned within the cholesterol lowering market, first, as monotherapy and second, in combination with statins. (Audibert, Tr. 4125-26; [SPX 231 at SP 002944]). Third, Audibert conducted an evaluation of the price at which Niacor-SR could be marketed. (Audibert, Tr. 4125-27). In making this determination, Audibert knew that Niacor-SR's position against the statins required that he be realistic in terms of pricing for Niacor-SR. (Audibert, Tr. 4126). As a result, he concluded that Niacor-SR would best be positioned as an inexpensive alternative to the statins and he selected a price of just half of atorvastatin, the generic name for Lipitor. (Audibert, Tr. 4126). Finally, Audibert projected what share of the market Niacor-SR could obtain at that price and positioning. (Audibert, Tr. 4126-27). Audibert concluded that Niacor-SR would compete as a low-priced, moderately effective product for the treatment of

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high cholesterol. (Audibert, Tr. 4126-27). From his experience in talking with cardiologists and health payers internationally, Audibert had learned that many countries with government funded health systems recognized the need to treat high cholesterol, but simply could not afford to treat significant portions of the population with the expensive statins. (Audibert, Tr. 4126-27).

250. Having identified the opportunity to position Niacor-SR as an inexpensive alternative to statins, Audibert still believed that Niacor-SR would only obtain an initial market share of .75%, rising for just two years to 1.5%, and then decreasing thereafter to a 1% share. (Audibert, Tr. 4127-29; SPX 2 at SP 16 00047).

251. Having estimated the overall size of the market and a market share for this product over a ten year period, Audibert used multiplication to determine projected sales. (Audibert, Tr. 4127). Audibert's formal written assessment for Niacor-SR, dated June 17, 1997, includes tables illustrating Audibert's annual projections of market size and market share, from which he calculated annual dollar sales. (Audibert, Tr. 4127-29); SPX 2 at SP 16 00046-47). The sales projected for each of these years, in millions, were:

Sales (\$)	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Millions	45	70	114	126	116	127	140	125	136	149

(SPX 2 at SP 16 00046-47).

252. On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. (Audibert, Tr. 4138-39; SPX 6). The annual profit and loss calculations were created by deducting from his sales forecasts, an estimated 10% cost of goods, as well as the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at \$ 22.8 million in the third year of sales. (SPX 6). Because Audibert did not know what royalty rate would be negotiated, his calculations represented the

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annual net profit before deducting the royalties to be paid to Upsher-Smith. (Audibert, Tr. 4139).

253. Following his evaluation of the Niacor-SR opportunity, Audibert prepared a written commercial assessment, as well as a written profit and loss projection on the basis of the sales he had projected in his commercial assessment. (SPX 2; SPX 6). Audibert provided a copy of each of these documents to Lauda. (Audibert, Tr. 4138-40; Lauda, Tr. 4345-46).

254. In his assessment, Audibert provided background information regarding the cholesterol lowering market, including the competitor products in that market. (SPX 2 at SP 16 00040-45). Audibert explained the current state of knowledge regarding niacin as an effective cholesterol lowering agent, as well as the difficulties that had hampered prior immediate release niacins (flushing) and sustained release niacins (association with hepatotoxicity). (SPX 2 at SP 16 00040-45). Audibert detailed the current size of the cholesterol lowering market, recent growth experienced in that market, and provided an assessment of why the growth of that market was expected to continue. (SPX 2 at SP 16 00040-45). Audibert identified his conclusion that a product opportunity existed for Niacor-SR, and on the basis of his conclusions, he provided a summary of his sales projections for Niacor-SR. (SPX 2 at SP 16 00040-45). Audibert attached to his assessment two tables which contained his detailed financial projections of both the future growth of the cholesterol lowering market and his sales projections for Niacor-SR in that market. (SPX 2 at SP 16 00046-47). Audibert concluded that Niacor-SR offers a \$ 100 [ILLEGIBLE WORD] million sales opportunity for Schering. (SPX 2, at SP 1600045).

255. Niacor-SR also offered strategic value to Schering in June 1997. Schering was developing ezetemibe for the cholesterol market, the projected launch of which was still several years away. (Audibert, Tr. 4094, 4108-09). Because Schering was planning to launch the largest product in company history in a market in which it had no presence, it was important for Schering to first establish a presence in that market in order to build a

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knowledgeable sales force capable of maximizing the launch of ezetimibe. (Audibert, Tr. 4108-11; Horovitz, Tr. 3622-23, 3659-66; Lauda, Tr. 4348-49; Russo, Tr. 3437-38).

iii. Audibert's sales projections for Niacor-SR were consistent with projections for Niaspan

256. In March 1997, Kos proceeded with an Initial Public Offering ("IPO") on the basis of projected sales of its primary product, Niaspan. (Patel, Tr. 7544; Egan, Tr. 7982; Kerr, Tr. 6982). Around the time of the IPO in the spring of 1997, several market analysts published projected U.S. sales for Niaspan reaching between \$ 220 million and \$ 250 million in the third year of sales. (Levy, Tr. 2072; SPX 226; Kerr, Tr. 6872-73; USX 535 at USL 11514; [Patel, Tr. 7674-75].)

257. In April 1997, Russo, Schering's senior director of marketing in charge of the negotiations with Kos prepared a range of forecasts of potential U.S. Niaspan sales. Russo forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731). Under this scenario, Russo projected that Schering could achieve \$ 134 million in sales in 2002, rising thereafter to \$ 193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iv. Schering determined that the value of Niacur-SR to Schering in June 1997 exceeded \$ 60 million

258. Following Audibert's evaluation, Lauda and Audibert met to discuss the written assessment and profit and loss statement, including the projected sales that Schering could expect from Niacor-SR, its projected market share, and assumptions underlying those projections. (Lauda, Tr. 4345-46; SPX 2; SPX 6). Lauda concluded that Schering could promote Niacor-SR and "easily garner" the market share that Audibert projected. (Lauda, Tr. 4347-49).

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259. Using the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher-Smith called for under the agreement, Schering performed its standard calculation of the economic value for this transaction which confirmed that Niacor-SR presented an economic value to Schering of between \$ 225 to \$ 265 million, and an internal rate of return of 43%. (SPX 26 at SP 16 00275). None of Complaint Counsel's witnesses challenged the validity of Schering's calculation that Audibert's financial projections for Niacor-SR represented an economic value to Schering of between \$ 225 to \$ 265 million, and a return on its investment of 43%. (SPX 26 at SP 16 00275).

260. Schering's expert on pharmaceuticals, Dr. Zola Horovitz, performed his own "conservative" calculations and concluded that Schering could have paid as much as \$ 100 million and still obtained a 35% internal rate of return and an economic value of \$ 205 million. (Horovitz, Tr. 3617-18). Upon review of the information he relied upon, Dr. Horovitz testified that, based on Schering's projections at knowledge in June 1997, the deal for Niacor-SR would be a good deal for Schering and would stand on its own two feet. (Horovitz, Tr. 3787).

261. Having concluded that the Niacor-SR opportunity presented a value to Schering in excess of \$ 60 million, Lauda advised Kapur of his conclusion and later provided him a copy of Audibert's written assessment and profit and loss projections. (Lauda, Tr. 4349; SPX 2; SPX 6).

4. Schering's And Upsher-Smith's post-deal conduct

a. Schering's internal preparations and communications with Upsher-Smith regarding availability of Niacor-SR data

262. Shortly after Schering's Board of Directors approved the Niacor-SR license, June 24, 1997, (CX 340), Schering began to get the Niacor-SR project organized. On July 2, 1997, Kapur informed Cesan that global marketing would take responsibility for Niacor SR, while Warrick, Schering's subsidiary, would

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oversee development of the generic products licensed from Upsher-Smith. (SPX 8). At the same time, Kapur notified Lauda that the Niacor-SR deal had been approved and that global marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. (SPX 7; Lauda, Tr. 4350).

263. Schering also contacted Upsher-Smith regarding Niacor-SR and other matters soon after the Schering Board approved the Upsher-Smith license agreement. (SPX 255; SPX 9). On June 30, 1997, Schering's in-house counsel for licensing, Paul Thompson, sent Upsher-Smith a draft of a more detailed Amendment Agreement that expanded on such issues as the supply and delivery of Niacor-SR and other licensed products. (SPX 255; Kralovec, Tr. 5050-51). On July 16, 1997, Kapur wrote to Troup regarding Schering's intention to schedule a visit to inspect Upsher-Smith's facility that manufactured cholestyramine, one of the generic products Schering had licensed from Upsher-Smith. (SPX 9).

264. Audibert attempted to arrange, through Mark Halvorsen, Upsher-Smith's Director of Clinical and Regulatory Affairs, a visit by someone from Schering's clinical research group to Upsher-Smith in order to review Upsher-Smith's data and discuss regulatory filing strategies. (SPX 241; Audibert, Tr. 4142, 4149-50). On August 21, 1997, Audibert updated Kapur on the Niacor-SR project, explaining that his efforts to arrange this trip to Upsher-Smith had been unsuccessful because of Upsher-Smith's delays in compiling the relevant clinical data and regulatory documents. (SPX 11; Audibert, Tr. 4154-55).

265. Schering continued to communicate with Upsher-Smith regarding its desire to obtain the Niacor-SR data. (SPX 10; SPX 12). On October 21, 1997, Kapur wrote to Troup, asking whether the Niacor-SR clinical data that Schering had expected by mid-October was available and attempting once again to set up a meeting for Schering to review the information at Upsher-Smith's offices. (SPX 12 at SP 05 00014; Audibert, Tr. 4156). A November 7, 1997 memo from Mr. Kapur to Audibert indicates

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that Troup had agreed that Upsher-Smith would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) were completed. (SPX 12 at SP 05 00013; Audibert, Tr. 4156).

b. Upsher-Smith's internal development efforts on Niacor-SR and communications with Schering

266. After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher-Smith about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. (Troup, Tr. 5481-83). By the end of June, Upsher-Smith and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher-Smith. (USX 732).

267. As of the summer of 1997, Upsher-Smith was going forward with its NDA and Upsher-Smith's primary activity was to complete the final study reports and the ISS/ISE. (Halvorsen, Tr. 3975). The patient phase of all four clinical studies had concluded well before June 1997 and Upsher-Smith was in the process of compiling the data. (Halvorsen, Tr. 3912).

268. In early June 1997, consistent with the FDA's agreement in March 1997 that Upsher-Smith only needed to conduct a single-dose PK test (Halvorsen, Tr. 3940-41; USX 0281). Upsher-Smith prepared a protocol for such a test and started on it immediately. (Halvorsen, Tr. 3941; SPX 331). To conduct the PK test, Upsher-Smith first had to be sure that it had validated a proper bioanalytical method for measuring the drug passed in urine. (Halvorsen, Tr. 3942-45). Upsher-Smith hired two contract research organizations ("CROs") to work separately in competition to develop a final methods validation. (Halvorsen, Tr. 3942-45; USX 562). Simultaneously, Upsher-Smith had them test the protocol with a pilot study using Slo-Niacin so that Upsher-Smith would have samples to use in developing the method for testing Niacor-SR. (Halvorsen, Tr. 3942-45).

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269. Upsher-Smith continued throughout the second-half of 1997 to hold its teleconferences with the CROs regarding the study reports, medical narratives and the accompanying medical narratives. (Halvorsen, Tr. 3975; USX 1146). Between June 20 and December 19, 1997, there were 19 more such conference calls. (USX 1146). As of July 22, 1997, the goal was to file the Niacor-SR NDA before the end of the year. (Halvorsen, Tr. 3985; USX 1188 at 093578).

270. During June and July 1997, Upsher-Smith was working on its Niacor-SR package insert to include with its NDA submission. (Freese, Tr. 4990; USX 308). By July 21, 1997, Upsher-Smith had developed a revised draft of its package insert. (Freese, Tr. 4990; USX 308). Upsher-Smith's draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. (Freese, Tr. 4990; USX 308 at 110477-9).

271. Prior to August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data in the first of several communications between the two representatives. (Halvorsen, Tr. 3976-77; USX 189). During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher-Smith had conducted with Niacor-SR for FDA approval--the two pivotal studies and the two follow on studies. (Halvorsen, Tr. 3976-77; USX 189). On August 14, 1997, Audibert sent Halvorsen a fax to arrange a meeting at Upsher-Smith for the week of September 15. (USX 189).

272. In August 1997, Upsher-Smith was still planning to file its NDA for approval of Niacor-SR at the end of 1997. (Halvorsen, Tr. 3977-78). By telephone call, Halvorsen informed Audibert that he did not believe that there would be clinical data available until late October, and that what Upsher-Smith would have at that time were the final reports from the individual studies, and not the ISS/ISE. (CX 780 at 00236).

273. On August, 15, 1997, Upsher-Smith mailed copies of the four protocols--the 115, 221, 837 and 955 clinical studies--to

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Audibert. (Halvorsen, Tr. 3979; USX 727). Mr. Audibert then forwarded this information to Schering's research institute. (CX 780 at 00236).

274. On October 27, 1997, a Schering licensing attorney faxed to Upsher-Smith's CFO, Mr. Paul Kralovec, a copy of the Amendment Agreement with Schering's proposed revisions. (SPX 217 at 0013). On November 12, 1997, Kapur's secretary, responded to Upsher-Smith's October 31 letter regarding the need for Schering to execute a broader confidentiality agreement covering the licensed products, including Pentoxifylline. (USX 218 at 135402).

c. Kos' stock plunge preceded Upsher-Smith's and Schering's decisions not to pursue Niacor-SR projects

275. In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States, which were considerably below what everyone had expected. (Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480). The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos' stock price, which had peaked around \$ 44 per share, plummeted to \$ 5 per share. (Troup, Tr. 5480).

276. Within a few weeks after Kos released the sales information for Niaspan, Upsher-Smith had pulled back on its ANDA project because in order to successfully go forward with a generic product, the branded product must attain a certain level of sales. (Halvorsen, Tr. 3956, 3964). An NDA was equally unpromising as Niacor-SR was a very similar product to Niaspan, which failed to achieve a large following. (Halvorsen, Tr. 3964). In December 1997, Upsher-Smith put its Niacor-SR development project "on hold status, pending evaluation of Kos marketing success." (SPX 302 at USL 16165).

277. Although Upsher-Smith decided not to go forward with its NDA for Niacor-SR in the United States, a December 16, 1997 fax reports that Halvorsen informed the Niacor-SR team that there

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was a possibility that the project would proceed in Europe through Schering. (USX 1226; Halvorsen, Tr. 3987-88). January 15, 1998 meeting minutes indicate that the Niacor-SR project was on hold with "only minimal activity" to continue in most departments. (CX 962 at USL 13253; Halvorsen, Tr. 4051). Halvorsen testified that Upsher-Smith's clinical department proceeded "full forward" at that point with efforts to complete the study reports. (Halvorsen, Tr. 4051). The January 15, 1998 meeting minutes indicate that this continuing work represented "a significant amount of resource hours" for Upsher-Smith. (CX 962 at USL 13252, USL 13253; Halvorsen, Tr. 4051). Upsher-Smith continued to communicate with its CROs in efforts to compile the integrated summary of safety and the draft clinical tables in January 1998. (Halvorsen, Tr. 3988-89; USX 1235).

278. Niaspan's performance in the marketplace was relevant to the Niacor-SR project because it provided a real world opportunity for Schering to test the market. (Audibert, Tr. 4144). By September 1998, Schering no longer believed that Niacor-SR would do as well as it had originally predicted. (Lauda, Tr. 4433-34; Audibert, Tr. 4143-44).

279. A subsequent discussion between Audibert, Kapur and Troup regarding Niacor-SR is summarized in a September 25, 1998 memo from Audibert to Mr. Lauda. (SPX 15). During this discussion, Troup stated that Upsher-Smith was not going forward with its NDA. (SPX 15; Audibert, Tr. 4159). Audibert's memo indicates that this raised some real issues in his mind about the potential commercial viability of Niacor-SR from his perspective. (SPX 15; Audibert, Tr. 4159). He noted that "in August 1998, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." (SPX 15). He also stated that Upsher-Smith's decision not to pursue its NDA would result in delay and a greater demand on Schering's resources if it proceeded with its European filings. (SPX 15).

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280. On October 6, 1998, Kralovec confirmed in a letter to Kapur that Upsher-Smith had suspended all research on Niacor-SR. (CX 1111; Kralovec, Tr. 5058-59; Lauda, Tr. 4428-29). Upsher-Smith cited the poor performance of Kos' Niaspan as one factor in its decision (Kralovec, Tr. 5061-62), as well as the fact that the FDA had requested that Upsher-Smith conduct an additional PK study, which would have delayed Upsher-Smith's NDA and resulted in the product coming to market two or three years behind the launch of Niaspan. (Lauda, Tr. 4429; CX 1111).

281. Schering abandoned its efforts to bring Niacor-SR to market for several reasons. (Audibert, Tr. 4144; Lauda, Tr. 4352-53). The Kos product continued to do poorly in the marketplace, telling Schering that marketing a sustained release niacin product was going to be more difficult than anticipated. (Audibert, Tr. 4144-45). Niaspan's poor performance in the United States had implications for Niacor-SR sales in Europe. (Audibert, Tr. 4145). The fact that Upsher-Smith had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together its international dossier than had originally been anticipated. (Audibert, Tr. 4145). Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. (Audibert, Tr. 4145). As a result, Schering decided not to pursue Niacor-SR further. (Lauda, Tr. 4407).

d. Upsher-Smith continued clinical work and medical writing wrap up and continued to communicate with Schering in 1998

282. Although Upsher-Smith decided in December 1997 to put on hold its plans to obtain FDA approval for Niacor-SR, this did not affect its clinical work on behalf of Schering. (Halvorsen, Tr. 3989). Upsher-Smith continued in 1998 to finalize the clinical study reports and put them in a usable form for Schering. (Halvorsen, Tr. 3989). During 1998, Upsher-Smith remained in contact with Schering-Plough regarding the licensed products. (USX 665, SPX 251; CX 1088; CX 1111).

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283. Throughout the first part of 1998, at Upsher-Smith's instruction, its CRO continued to work on the methods validation for the single-dose PK protocol. (Halvorsen, Tr. 3943-44; SPX 331). The CROs working on the reports and medical writing continued their work through March of 1998, and Upsher-Smith's research and development team continued to have their regular telephone conferences to supervise and assist that work. (Halvorsen, Tr. 3924-25:4; 3944-45; USX 1230). Between January 1, 1998 and May 1998, members of Upsher-Smith's research and development team participated in a dozen such calls. (USX 1230; USX 1232 at 903845; Halvorsen, Tr. 3988-95).

284. In a meeting in March of 1998 in the office of Upsher-Smith's president Mr. Troup, Dr. Halvorsen was informed that Schering was not going to seek European approval. (Halvorsen, Tr. 3924-25).

285. On May 13, 1998, a CRO provided to Upsher-Smith the final draft of the Niacor-SR 92044 follow-on study and the related medical narratives. (USX 1265 at 093775; CX 1019). On November 4, 1998, Upsher-Smith received from a CRO its 508-page report containing the final methods validation for the PK test required by the FDA. (Halvorsen, Tr. 3943-44; SPX 333 at 165879). The total cost to Upsher-Smith of performing this final methods validation was \$ 400,000. (Halvorsen, Tr. 3944). Upsher-Smith was also spending money on its multiple CROs for their clinical work in completing the final study reports, the ISS and the ISE. (Halvorsen, Tr. 3944-45).

286. All totaled, from 1991 through 1998, Upsher-Smith spent \$ 15-16 million on developing Niacor-SR--four times as much alone than all other product development projects, and more than 80 percent of Upsher-Smith's total research budget during that period. (Kralovec, Tr. 5010-11; Halvorsen, Tr. 3902, 3995; Troup, Tr. 5475).

287. In September 1998, Upsher-Smith's President and Warrick's President, Mr. Kapur, had a discussion regarding the status of Niacor-SR. (Troup, Tr. 5608; Audibert, Tr. 4158-59; CX

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1088 at 006-7). Troup reported that Upsher-Smith was not planning to file its NDA for FDA approval. (CX 1088; CX 1111 at SP 05 006-7; Troup, Tr. 5610). Mr. Troup explained that Upsher-Smith was concerned that Kos's Niaspan product had not been successful, even though Kos had invested considerably more sales and promotion effort in the United States than Upsher-Smith planned. (CX 1088 at SP 05 006-7; Troup, Tr. 5480-81; Audibert, Tr. 4159-60).

288. Based on what he knew at the time, Troup also explained that Niaspan appeared to be marginally better than Niacor-SR. (CX 1111). Upsher-Smith believed that because Niaspan had received the results indications for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. (Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60).

289. As Kapur had requested, on October 6, 1998 Paul Kralovec, Upsher-Smith's Chief Financial Officer, provided Kapur written confirmation of Upsher-Smith's decision to suspend its efforts on Niacor-SR. (CX 1111). In the letter, which was also copied to Troup, Kralovec again confirmed the reasons for Upsher-Smith's decision not to proceed with U.S. approval. (CX 1111). He again explained that based on Kos's approval, Upsher-Smith would have been two to three years behind the launch of Niaspan. (CX 1111).

5. Complaint Counsel has not demonstrated that the value of Niacor-SR and the other pharmaceutical products was not \$ 60 million

a. Dr. Levy's criticism of the terms of the license fees

290. Dr. Levy did not prove that the terms of the deal were "grossly excessive" because he performed no quantitative analysis of the value of Niacor-SR. (See Levy, Tr. 2055-64). Dr. Levy rejected the standard practice of using discounted cash flows to determine the value of a drug such as Niacor-SR. (Levy, Tr.

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2059). As a result, Dr. Levy could not provide testimony as to the value of Niacor-SR--he admitted he could not testify whether a license for Niacor-SR was worth zero, \$ 10 million or \$ 100 million. (Levy, Tr. 2063).

291. Dr. Levy conceded that he had done no quantitative analysis of Niacor-SR. (Levy, Tr. 2057-59). Dr. Levy rejected using net present value ("NPV") analysis to value license opportunities for late stage pharmaceutical products. (Levy, Tr. 2155). He described conducting NPV analysis to determine the value of a pharmaceutical drug as "guesswork" because he believed that one "does not have a clue" as to what the risk factor is and testified that "nobody is going to rely" on such NPV calculations. (Levy, Tr. 2155-57). He testified that an NPV analysis of a late-stage pharmaceutical product that was not on the market was "GIGO," which he explained meant "Garbage in, garbage out." (Levy, Tr. 2157).

292. Other witnesses who testified in relation to NPV analysis confirmed its utility in valuing licenses, including Complaint Counsel's own witnesses. Dr. Max Bazerman, Complaint Counsel's expert witness, testified that in his 15 years of meetings with pharmaceutical executives, none have ever expressed the view that "discounted cash flows are junk or garbage or worthless or words to that effect." (Bazerman, Tr. 8555). Complaint Counsel's expert Professor Bresnahan confirmed that NPV determinations are used to value a stream of payments and that NPV analysis is a common concept in economics and finance. (Bresnahan, Tr. 662). Upsher-Smith's expert Dr. William Kerr testified that NPV analysis is "the most common method for valuing intellectual property." (Kerr, Tr. 6277-78). Schering's expert Dr. Zola Horovitz explained that the purpose of a net present value analysis calculation is to determine what a project will return as far as profits and cash flow to a company. (Horovitz, Tr. 3615). Horovitz testified that he conducted an NPV analysis based on the information Upsher-Smith provided to Schering and concluded that Schering could have paid up to \$ 100 million for the Niacor-SR license. (Horovitz, Tr. 3612-13).

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293. Not only did Dr. Levy not perform a financial evaluation of Niacor-SR, he did not do a financial evaluation of any of the five other products licensed to Schering. (Levy, Tr. 2059). Dr. Levy admitted that he did not know as to each of the five other products licensed under the June 17 Agreement whether each product was worth zero, \$ 10 million or \$ 100 million. (Levy, Tr. 2062-63). Dr. Bresnahan concedes that each of these 5 other products had value for Schering. (Bresnahan, Tr. 951, 953, 956).

294. Dr. Levy admitted that he also did not do any valuation analysis on the production or supply rights for the six licensed products that Upsher-Smith granted to Schering in Paragraphs 7-10 of the license agreement. (Levy, Tr. 2059-63). In fact, Dr. Levy was unaware that Schering had received any production rights from Upsher-Smith under the agreement. (Levy, Tr. 2059-60).

295. Dr. Kerr, Upsher-Smith's valuation expert, performed a valuation of the drugs licensed in the June 17 Agreement other than Niacor-SR and determined that they were worth \$ 10.1 million as of June 1997. (Kerr, Tr. 6300-02).

296. Instead of offering an opinion on the value of the license fees, Dr. Levy testified only that the fees were "grossly excessive." This conclusion was based in part on his belief that the \$ 60 million up-front payment was larger than any previous license fee in the history of the pharmaceutical industry. (Levy, Tr. 1329-30). A comparison of the payment terms of various deals requires more than an isolated consideration of the up-front license fees. In performing his up-front-payments-only analysis, Dr. Levy ignored provisions relating to how the parties agreed to split future revenues generated from the product and ignored Schering's consideration of its costs to bring the product to market. (Levy, Tr. 1337, [Tr. 1464-66]; CX 1604).

297. [redacted] (Levy, Tr. 1329; SPX 92 at SP 00195). [redacted] (Levy, Tr. 1329). [redacted] [(Lauda, Tr. 4595; CX 1402 at SP 074847)], [redacted] [(CX 1468 at SP 074431-32)],

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[redacted] [(CX 1468 at SP 074433)]. [redacted] [(Lauda, Tr. 4450-51)], [redacted] [(CX 1397 at SP 06958)]. [redacted]

298. As noted by Mr. James Egan, Complaint Counsel's rebuttal witness from Searle Pharmaceuticals, there is risk involved in making a large up-front payment (Egan, Tr. 7983), [redacted] [(CX 1338 at SPCIDZ ID 12723)], [redacted] [(Lauda, Tr. 4512-13)], [redacted]. [(Lauda, Tr. 4599-4601)].

299. In evaluating a licensing opportunity, Schering analyzes the total investment required to bring a product "to a state of registration," which includes (1) research and development expenditures required to bring a product to the approvable stage; and (2) payments that are contingent upon pre-approval events, such as successful completion of phase II studies. (Lauda, Tr. 4365-66). With the results of the Phase III clinical trials already in Schering's hands, Niacor-SR was much further along in development than most of the other Schering deals analyzed by Dr. Levy. [(Levy, Tr. 1464-65)]; CX 1604; [(Lauda, Tr. 4405, 4468)]; SPX 2267; Horovitz, Tr. 3766). [redacted] [(Lauda, Tr. 4465-68)]; (SPX 2264).

300. Schering also regularly considers economic value when considering an in-licensing opportunity. (Lauda, Tr. 4361-63). The economic value is the estimated economic return Schering expects to realize on a project. (Lauda, Tr. 4362). [redacted] [(Lauda, Tr. 4450-51)], [redacted] [(Lauda, Tr. 4479, 4481, 4483); CX 1397)], [redacted] [(Lauda, Tr. 4478-79)]. [redacted]. [(CX 1397 at SP 06958)] (SPX 92 at SP 00195). [(Lauda, Tr. 4481-83)]; (19 Tr. 4479-83; CX 1397 at SP 069948).

ii. Dr. Levy's criticism of Schering's due diligence

301. Dr. Levy testified that, in his opinion, the level of due diligence performed by Schering for Niacor-SR was "strikingly superficial." (Levy, Tr. 1341-42; CX 1597). In explaining how he reached this conclusion, Dr. Levy testified that he had put himself in Schering's position in June 1997 to "try to ascertain what I might have done had I seen what they saw." (Levy, Tr. 1342).

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302. In support of his testimony that the due diligence performed for Niacor-SR was "strikingly superficial," Dr. Levy compared the volume of due diligence for Niacor-SR to the volume of due diligence from two other Schering evaluations. [(Levy, Tr. 1376-78, 1492, 1516, 1886-87)]. In selecting his two yardsticks, Dr. Levy concedes that he simply selected these comparators from a "list," and that he did not review "in toto" all 33 license evaluations for which Schering produced documents to Complaint Counsel. [(Levy, Tr. 1377, 1524)].

303. Aside from his general criticism of the volume of due diligence performed for Niacor-SR, Dr. Levy identified two specific aspects of due diligence that he believes should have raised concerns for Schering: (1) dietary supplement forms of sustained release niacin had been associated with liver toxicity; and (2) the FDA had requested that Upsher-Smith perform an additional 17-day, single-dose pharmacokinetic ("PK") study in 30 patients. (Levy, Tr. 1317, 1388; Halvorsen, Tr. 4001-03; SPX 0331). However, the liver toxicity issue had already been specifically evaluated by Schering. (Audibert, Tr. 4119-22). Also, Dr. Levy described the requirement of a PK study as follows: "Doing a pharmacokinetic study in Schering-Plough is like falling off a log. I mean they do them routinely." (Levy, Tr. 1388). Lauda testified that the PK study was, at best, a very minor issue that would not even have "caused a blip on the radar." (Lauda, Tr. 4516-17, 4421). Moreover, at the time of the license agreement for Niacor-SR, Upsher-Smith had already built the PK study into the December 1997 NDA filing timetable upon which Schering relied. (Horovitz, Tr. 3728, 3793-94).

304. The amount of due diligence that Schering performs in evaluating a licensing opportunity depends on the nature of the opportunity. (Russo, Tr. 3432-33; [Lauda, Tr. 4574]). Schering does not use any standard approach in evaluating a licensing opportunity. (Russo, Tr. 3432-33). Generally, the higher the risk involved with a particular product, the more involved Schering's review process will be. (Russo, Tr. 3432-33).

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305. Unlike other products Schering has evaluated, Niacor-SR was a very straightforward product in a market with which Schering was intimately familiar. [(Lauda, Tr. 4599-4601)]; Audibert, Tr. 4093-98, [4299-4304], 4137). Niacor-SR was a late stage Phase III product, and Schering was able to conduct its evaluation on the basis of the results of the Phase III pivotal trials. (Audibert, Tr. 4113-14; [Lauda, Tr. 4599-4600]; Horovitz, Tr. 3682, 3717; CX 1042). Niacor-SR's active ingredient, niacin, is an old and well-known compound with an established product profile. (Audibert, Tr. 4137-38; [Lauda, Tr. 4599-4600]; Horovitz, Tr. 3681). Niacor-SR had "proof of principle" in that niacin has long been known to be effective in the treatment of high cholesterol, the exact indication targeted for Niacor-SR. (Audibert, Tr. 4116-17; [Lauda, Tr. 4599-4600]). In fact, as a result of niacin's known efficacy profile, the FDA had advised Upsher-Smith during the development of Niacor-SR that "there is no question that niacin is effective," and that "efficacy was considered almost a non-issue." (CX 1376 at Upsher-Smith FTC 127098; CX 1371). On the basis of these considerations, Dr. Horovitz testified that in evaluating a drug like Niacor-SR, he would expect that a knowledgeable person could perform the requisite due diligence more quickly than would be the case with other licensing evaluations. (Horovitz, Tr. 3682).

306. Audibert was already familiar with cholesterol lowering drugs--including niacin--as a result of his detailed evaluation of the cholesterol lowering market as part of his work on Schering's blockbuster pipeline drug, ezetimibe. (Audibert, Tr. 4095-4100). Niacor-SR was a known drug reformulated using sustained release technology to overcome a known side effect, a method of development with which Audibert had gained substantial expertise throughout his career. (Audibert, Tr. 4082-89; Horovitz, Tr. 3679-80). Audibert knew from his evaluation of Kos' Niaspan just months earlier that the FDA was on the verge of approving another sustained release niacin, and the results of the pivotal trials for Niacor-SR confirmed that Upsher-Smith had similarly succeeded in developing a safe and effective sustained release niacin. (Audibert, Tr. 2453-54 (Audibert Dep.); [Lauda, Tr. 4512-13]; Horovitz, Tr. 3679-80).

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307. Based on Audibert's evaluation of Niacor-SR, Schering did not believe that additional due diligence was required. [(Lauda, Tr. 4516]; Andibert, Tr. 4137).

308. Dr. Levy was unfamiliar with the National Cholesterol Education Program ("NCEP"), which sets the nationally accepted guidelines for cholesterol lowering in the United States and which were relied on throughout the Kos and Upsher-Smith niacin research documents and studies. (Levy, Tr. 8404-05). Dr. Levy also demonstrated his unfamiliarity with the leading studies relating to niacin. (Levy, Tr. 8401-03, 8406).

309. Dr. Levy was mistaken in both his expert report and his trial testimony as to the type of PK study Upsher-Smith needed to complete to get its NDA for Niacor-SR approved--he was under the misimpression that a multiple dose PK study was required. In fact, by March 1997 the FDA had confirmed that Upsher-Smith only had to perform a single-dose PK study. (Levy, Tr. 2182-83; CX 917 at 107426; USX 281).

310. Dr. Levy admitted that he had not seen (and therefore had not considered) the 200-plus page final methods validation report for the Niacor-SR PK test that the CRO had been developing between summer 1997 and fall of 1998. (Levy, Tr. 2131; SPX 333 (methods validation report); Halvorsen, Tr. 3943-45 (describing MDS Harris work on report); USX 556 (December product update cited by Levy stating "MDS Harris will complete work through method validation"))).

311. At the time he testified, Dr. Levy believed Upsher-Smith had only conducted the two Phase III pivotal clinical studies and was unaware that Upsher-Smith had also conducted the two longer term follow-on Phase III studies, the 900837 and the 920944 studies. (Levy, Tr. 2079-80).

312. When asked whether he took into account any follow-on studies, Dr. Levy indicated he had focused on the materials provided to Schering and believed he knew what Schering knew at the time about the status of Upsher-Smith's clinical studies.

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(Levy, Tr. 2079-80). However, all four clinical studies are referenced in the confidential presentation Upsher-Smith provided to Schering--including the two follow-on studies--and the presentation indicated that Upsher-Smith had completed or was completing the final study reports for all four. (CX 1042 at 0079). Dr. Levy conceded on cross-examination that all four reports were referenced in the materials Schering received. (Levy, Tr. 1830-31).

313. In his expert report, Dr. Levy stated that the elevated liver enzyme levels indicated in the package Schering received from Upsher Smith "would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination, in my opinion, would have included at least: Examination of liver biopsies in patients treated with Niacor-SR . . ." (Levy, Tr. 1785-99). A liver biopsy is performed by inserting through the skin of the subject a seven-inch hollow needle, approximately 18-gauge, with a bore on the point that fills the bore of the needle. (Levy, Tr. 1785-99). The needle is pushed through into the liver, a chunk of the liver is removed using suction, and then the needle is removed. (Levy, Tr. 1795-96).

314. To perform such liver biopsies, Upsher-Smith would have been required to track down patients who had completed the study years earlier and re-dose those patients in an attempt to replicate those elevations, and then perform a surgical procedure to remove a piece of the patients' livers to determine whether that re-dosing had caused liver damage. (Levy, Tr. 1786-87, 1796-97). Dr. Levy testified at his deposition that it would have been "quite reasonable" for Schering to ask Upsher-Smith to do this. (Levy, Tr. 1786-87). During cross-examination, however, Dr. Levy admitted that he "probably overstated" the opinion expressed in his expert report and deposition testimony regarding the requirement of liver biopsies. (Levy, Tr. 1790, 1793, 1798-99). Dr. Horovitz explained his experience with the clinical trials for one of the statins where a Japanese company had inquired about the possibility of taking liver biopsies of patients during the

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clinical trials, and the FDA considered that request "ridiculous." (Horovitz, Tr. 3708).

iii. Dr. Levy's criticism of the post deal conduct

315. Dr. Levy testified that his opinion that the "\$ 60 million was not for Niacor-SR" rests in part on the fact that after the June 17, 1997 licensing transaction neither party showed any serious interest in marketing Niacor-SR. (Levy, Tr. 1822-23). In his report, Dr. Levy wrote that there were almost no communications between Schering and Upsher-Smith after the execution of the agreement. (Levy, Tr. 2079-80).

316. Levy's conclusion in his report and testimony that there were almost no communications between Schering and Upsher-Smith following the June 17, 1997 Agreement is contrary to the record evidence. (Levy, Tr. 2079-80). There were no fewer than 2 meetings and 21 other documented communications between Schering and Upsher-Smith in 1997 after Upsher-Smith and Schering's licensing agreement and the record indicates it is likely there were other undocumented telephone calls. The communications continued into 1998. (F. 262-65).

317. Dr. Levy admitted that in reaching his opinion regarding Upsher-Smith's post-June 1997 efforts on Niacor-SR, he had not reviewed any of the more-than 80 minutes and agendas documenting the more-than 40 teleconferences Upsher-Smith had held with the CROs between June of 1997 and May of 1998 contained in USX 1178 through USX 1266. (Levy, Tr. 2099-2102, 2127). Those minutes detail the ongoing work being done by Upsher-Smith and the CROs to finalize the individual study reports, to compile the ISS/ISE and to wrap up the project. (Levy, Tr. 2099-2102, 2127). Those ClinTrials teleconference minutes and agenda memorialize that in December of 1997, Upsher-Smith had informed ClinTrials that Upsher-Smith was not going forward with filing the NDA, but that its European partner (Schering) might be proceeding. (USX 1259 at 093868; USX 1260 at 093790).

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318. Based on the mistaken belief that Upsher-Smith had stopped its clinical work on Niacor-SR, Dr. Levy testified it was his belief that the Upsher-Smith went almost a year without telling Schering that Upsher-Smith had decided not to pursue its U.S. submission--a decision Dr. Levy found "inconceivable." (Levy, Tr. 1394). Dr. Levy admitted, however, that he had been unaware of the ClinTrials documents indicating not only that Upsher-Smith had continued the clinical work into May of 1998, but that Upsher-Smith understood in March of 1998 that Schering was not going forward with its European submission. (Levy, Tr. 2099-2102, 2127; USX 1259 at 093868; USX 1260 at 093790).

b. Professor Bresnahan

319. Complaint Counsel offered the testimony of Professor Timothy Bresnahan, Professor of Economics. Bresnahan did not perform an economic valuation of any of the drugs licensed from Upsher-Smith to Schering. (Bresnahan, Tr. 950-57). He did not do a valuation analysis of Niacor-SR, pentoxifylline, Prevalite, the Klor Con products, or the supply agreement. (Bresnahan, Tr. 950-57). Professor Bresnahan also did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of \$ 225 - 265 million presented to Schering's Board of Directors. (Bresnahan, Tr. 975-78). Instead, Bresnahan utilized a "revealed preference" test and a market test to opine on the value of Niacor-SR. (F. 320-22).

i. The "revealed preference" test

320. Professor Bresnahan applied the "revealed preference" test to opine that the \$ 60 million payment was not for the Niacor license. Professor Bresnahan's opinion was that Schering's decision not to pay Kos for the right to co-market Niaspan revealed that Schering would not pay \$ 60 million for a license for any sustained-release niacin product. (Bresnahan, Tr. 582, 596-98; CX 1578).

321. Schering's decision to discontinue discussions with Kos with respect to a potential co-marketing arrangement was made

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for reasons that did not apply to its license transaction with Upsher-Smith. First, Schering was to receive at most half the profits from sales of Niaspan. As Professor Bresnahan conceded, this meant that the projected NPV of Schering's interest in Niaspan profits was \$ 127 million. (Bresnahan, Tr. 1115-16; CX 558; Russo, Tr. 3529-30). On the other hand, Schering was to receive all of the Niacor-SR sales after deducting a small royalty. (Levy, Tr. 1329; SPX 92 at SP 00195). As Professor Bresnahan conceded, the projected NPV of Schering's interest in the Niacor-SR sales was \$ 225-\$ 265 million. (Bresnahan, Tr. 1117; [Lauda, Tr. 4478-79]; SPX 26 at SP 16 00275). Second, Kos' demands from a co-promotion arrangement were high. Kos insisted that under any arrangement Schering would have to guarantee a significant number of primary details for Niaspan. (Patel, Tr. 7531, 7554; CX 769). Kos also wanted guarantees with respect to the level of sales call activity. (Russo, Tr. 3451). Third, Kos wanted to retain most of the control over how the product was marketed. (Bresnahan, Tr. 1112). Fourth, Kos insisted on booking sales or making Schering pay money in order to book sales. (Patel, Tr. 7556). And fifth, the Kos people were proving to be very difficult to work with. (Bresnahan, Tr. 1122).

322. The substantial, reliable evidence presented by Schering demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. (F. 217-19). This evidence refutes the conclusion Professor Bresnahan reached using his "revealed preference" test. (F. 320-21).

ii. The market test

323. Professor Bresnahan testified that he applied a "market test" to prove that the \$ 60 million was a payment for delay, and not for Niacor-SR. Professor Bresnahan's theory was that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, the "market test of the \$ 60 million payment is failed." (Bresnahan, Tr. 601-02). Bresnahan's conclusion that the Niacor-SR license was not

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worth \$ 60 million was based on his application of this "market test."

324. Professor Bresnahan had never before applied this market test in the context of pharmaceutical licensing, and he did not understand, when he applied it, how Schering normally goes about deciding what to pay for a license. (Bresnahan, Tr. 1125). When applying his market test, Professor Bresnahan did not know whether Schering customarily knew or cared what other companies were bidding for a product. Lauda explained, there is never a "market price" for a licensing opportunity. Schering generally does not know what other companies are bidding, and Schering's determination of how large a bid to make is driven by the company's own internal assessments. (Lauda, Tr. 4374-75). Complaint Counsel's rebuttal witness, Egan, (Searle) testified that one company may value a licensing opportunity differently from another. (Egan, Tr. 7964). These differences in valuation are attributable to varying subjective criteria. (Egan, Tr. 7964).

325. During the 30 days preceding Schering's license of Niacor-SR, Upsher-Smith had received expressions of interest from a number of European companies. (Halvorsen, Tr. 3970-73). At the conclusions of the June meetings in Europe, those companies indicated that they would review Niacor-SR and contact Upsher-Smith, but not within the following month. (Halvorsen, Tr. 3974).

326. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR licence. (F. 243-57). The evidence presented by Schering that Niacor-SR was worth \$ 60 million to Schering in June 1997 refutes the conclusion Professor Bresnahan reached using his market test.

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H. ESI's Micro-K20 and Patent Litigation**1. ESI's ANDA and the initiation of patent litigation**

327. In 1995, ESI Lederle, Incorporated ("ESI"), a division of American Home Products ("AHP") sought approval from the FDA to market Micro-K20, a generic version of Schering's sustained release potassium chloride tablet, K-Dur 20. (SPX 678; Miller, Tr. 3320). On December 22, 1995, ESI submitted an ANDA to the FDA that referenced K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. (Schering Answer P51; AHP Answer P51).

328. On December 29, 1995, ESI notified Schering of its Paragraph IV certification containing data from a bioequivalent study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20 tablets. (CX 419 at SP 06 00052; Schering Answer P51). The notification letter stated that the '743 patent would not be infringed by the AHP generic product since it "[did] not contain potassium chloride crystals coated with a mixture of ethylcellulose and hydropropylcellulose or with a mixture of ethylcellulose and polyethylene glycol, as disclosed and claimed in U.S. Patent 4,863,743." (CX 419 at SP 06 00052; SPX 678 at 1).

329. On February 16, 1996, within 45 days of receiving this letter, Schering's Key Pharmaceuticals division sued ESI for "willful and deliberate" infringement of the '743 patent, as contemplated under 21 U.S.C. § 355(j)(5)(B)(iii). (Miller, Tr. 3319-20). Schering sought an injunction in the U.S. District Court for the Eastern District of Pennsylvania that would have prevented ESI from marketing its generic version of K-Dur 20 for the remaining life of the '743 patent. (Miller, Tr. 3319-21; SPX 679).

330. ESI filed an answer and counterclaim for a declaratory judgment, alleging non-infringement and invalidity of the '743 patent. (SPX 680).

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331. No evidence or testimony was offered to show that Schering's filing of the patent litigation against ESI was not initiated for the legitimate purpose of defending its patent.

2. Settlement Negotiations

332. The parties first began discussing a possible settlement of the case in October 1996. (Herman, Tr. 2487). At a status conference, the presiding judge, Judge DuBois, suggested that the parties participate in a mediation session with a U.S. magistrate judge. (Herman, Tr. 2487). On October 16, 1996, both Key and ESI agreed to participate in mediation. (Herman, Tr. 2495; SPX 73). The magistrate judge appointed to participate in the mediation was Judge Rueter. (Herman, Tr. 2486). The mediation process with Judge Rueter ultimately lasted approximately 15 months. (Herman, Tr. 2486).

333. Throughout the course of the litigation between Schering and ESI, Judge DuBois made it clear that he wanted the parties to settle the case. (SPX 1222 at 53:13-25 (Alaburda I.H.)). Judge DuBois brought up settlement every time he talked to the parties, usually as the first order of business. (SPX 1222 at 73:3-16 (Alaburda I.H.)).

334. The parties participated in a settlement conference on November 19, 1996 in Judge Rueter's chambers. (Herman, Tr. 2497; SPX 77).

335. On December 10, 1996, Schering proposed to ESI that they enter into a co-promotion venture in which Schering and ESI would jointly fund and manage a third-party workforce in marketing K-Dur 20. (Herman, Tr. 2503-04; CX 1482 at 67 (Alaburda I.H.); CX 1494 at 101 (Driscoll I.H.); SPX 76).

336. ESI rejected the proposal on February 20, 1997, stating that, as a generic manufacturer, ESI did not have a sales and detail force capable of selling and marketing K-Dur 20. (Herman, Tr. 2504; CX 1482 at 70 (Alaburda I.H.); CX 1492 at 56 (Dey I.H.); CX 457).

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337. Eight days later, on February 28, 1997, another mediation session took place in Judge Rueter's chambers. (Herman, Tr. 2504; SPX 1202).

338. Following the February 1997 mediation session, the parties continued to discuss settlement proposals. On March 12, 1997, Judge DuBois sent a letter to counsel stating that he understood from Judge Rueter that settlement negotiations were continuing, and expressing his hope that the parties would settle. (Herman, Tr. 2513; SPX 1198).

339. On March 19, 1997, Mr. Paul Heller, ESI's outside counsel, wrote Mr. Anthony Herman, Schering's outside counsel, a letter stating that he had been advised that Schering's copromote proposal "raises considerable antitrust risks." (Herman, Tr. 2513; CX 458). The letter noted, again, that ESI was amenable to an arrangement whereby Schering would pay ESI and ESI would receive a license to enter the market in the future. (Hoffman, Tr. 2659-60; CX 458). Schering explained to ESI that this proposal was unacceptable. (Hoffman, Tr. 2631-32).

340. On April 18, 1997, Herman sent a letter to Judge Rueter on behalf of both Schering and ESI reporting on the state of the settlement efforts as being at "a standstill." (Herman, Tr. 2514; CX 459; CX 1492 at 129 (Dey I.H.)).

341. On August 20, 1997, Judge Rueter held a third mediation session in his chambers. (Herman, Tr. 2515; SPX 552).

342. Following the August 20, 1997 mediation session, on September 24, 1997, Heller sent a letter to Herman. (Herman, Tr. 2519; SPX 94). That letter projected the amount of profits that ESI believed it would earn if it were to win the case. (Herman, Tr. 2519; SPX 94, at SP 13 00004). ESI projected that, with the simultaneous launch of three generic versions of K-Dur 20, ESI's generic would earn over \$ 15 million in sales in the first year on the market. (SPX 94, at SP 13 00004). ESI projected that its generic version of K-Dur 20 would earn over \$ 25 million in sales in its second year on the market, over \$ 28 million in its third year

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on the market, over \$ 24 million in its fourth year on the market, and over \$ 23 million in its fifth year on the market. (SPX 94, at SP 13 00004).

343. Schering was willing to discuss other opportunities that were mutually beneficial to the parties apart from an outright payment to ESI. (Kapur, Tr. 1431; SPX 1242 at 125-27 (Kapur Dep.)). Mr. Martin Driscoll, then Vice President of Marketing and Sales for Key, discussed several such opportunities with ESI, including co-marketing Schering's products. (CX 1510 at 140 (Kapur I.H.); Kapur, Tr. 1431).

344. On October 14, 1997, Dr. Michael Dey, CEO of ESI, wrote a letter to Kapur, the head of Schering's generic division, to discuss a proposal for ESI to license several products to Warrick for overseas sale. (Herman, Tr. 2519; CX 465; CX 1482 at 121-24 (Alaburda (I.H.)). Those two products were enalapril and buspirone. (Herman, Tr. 2519-20; CX 1482 at 122-23 (Alaburda I.H.); SPX 1242 at 125-27 (Kapur Dep.)).

345. The next mediation session occurred on October 27, 1997 in Judge Rueter's chambers. (Herman, Tr. 2520). No settlement between the parties was reached that session. (Hoffman, Tr. 2618; Herman, Tr. 2520).

346. Another settlement conference was scheduled for November 17, 1997. (CX 468). On November 12, 1997, Herman sent Judge Rueter a letter expressing Schering's position that it would be a waste of the Court's and the parties' time to proceed with the scheduled settlement conference. (Herman, Tr. 2521; CX 468). At that point, ESI had told Schering that it was no longer interested in a co-promotion arrangement. (Herman, Tr. 2522; CX 468). This was the last time the copromote concept was raised. (Herman, Tr. 2522). The letter informed Judge Rueter that ESI had stated it was unwilling to agree to Schering's copromote proposal because of antitrust concerns. (Herman, Tr. 2522; CX 468). ESI responded that although ESI was not interested in a copromote, the parties were considering separate licensing opportunities. (SPX 1195).

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347. Herman's letter also addressed Schering's concerns that ESI lacked a potentially marketable product, informing Judge Rueter that Schering was unwilling to make another settlement offer until ESI demonstrated that it has a bona fide 20 milliequivalent potassium chloride product that, but for the lawsuit, would receive FDA approval. (Herman, Tr. 2522; CX 468).

348. The proposed November 17, 1997 settlement conference was postponed. (Herman, Tr. 2521).

349. ESI then provided Schering with information related to the current FDA approval status of ESI's proposed generic version of K-Dur. (Herman, Tr. 2523; SPX 82). On December 15, 1997, Mr. Herman summarized this information in a letter to ESI's counsel. Mr. Herman's December 15, 1997 summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version of K-Dur 20. The main problem ESI had involved a study included in the ANDA designed to demonstrate ESI's proposed generic was bioequivalent to K-Dur 20. (CX 469; Herman, Tr. 2523). The bioequivalence study had been performed in 1989. (CX 469; Herman, Tr. 2523-24). The FDA found five different deficiencies with regard to the study. (CX 469; Herman, Tr. 2523-24). ESI did not respond to the FDA regarding the deficiencies until May 14, 1997. (CX 469; Herman, Tr. 2524). On August 6, 1997, FDA rejected ESI's response to the five deficiencies in ESI's bioequivalence study. (CX 469; Herman, Tr. 2524). ESI began a new bioequivalence study on December 8, 1997, a week before the December 15, 1997 summary. (CX 469; Herman, Tr. 2524).

350. Two days later, in a December 17, 1997 letter from Schering to ESI, Schering proposed to settle the lawsuit by providing ESI with a license to market ESI's proposed generic version of K-Dur, effective December 31, 2003. (Hoffman, Tr. 2638-39; Herman, Tr. 2525; CX 470).

351. The December 17, 1997 letter stated:

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We propose to settle the case based on the following:

(1) Schering shall grant ESI a royalty-free license under the '743 patent to make, use, offer for sale and sell its Micro-K 20 potassium chloride product in the United States effective December 31, 2003. Until that date, ESI shall not make, use, offer for sale or sell its micro-K product.

(2) ESI will acknowledge infringement and validity of the '743 patent in a consent judgment.

(CX 470; Herman, Tr. 2525-26).

352. In the same December 17, 1997 letter, Schering also proposed that:

As an additional matter, ESI shall grant Schering, including its designee, exclusive licenses for buspirone, enalapril, and three other products under development by ESI to be mutually agreed upon by the parties. . . . In exchange for the licenses described in the unnumbered paragraph above, Schering shall pay ESI an up-front payment of \$ 5 million and a 5 percent royalty on annual sales for ten years post-approval.

(CX 470; Herman, Tr. 2526).

353. ESI responded to Schering's offer on December 22, 1997, accepting the December 31, 2003 entry date:

The general structure of your December 17 proposal is acceptable with the following modifications. The effective date of the license under the '743 patent should be December 31, 2003, or whenever a generic is placed on the market, whichever occurs earlier. . . . ESI will be able to market in the United States if the

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'743 Patent is invalidated or rendered unenforceable by another party.

(CX 473; Herman, Tr. 2527; Hoffman, Tr. 2639). ESI also agreed to acknowledge validity and enforceability of the '743 patent, but would not acknowledge that its product infringed. (Herman, Tr. 2528; CX 473).

354. The date of December 31, 2003 referred to in the letters differs from the date for ESI's product entry in the final agreement by one day. (Herman, Tr. 2525; CX 470; CX 473; CX 479). In the final agreement, the date agreed upon for ESI's product entry was January 1, 2004. (Herman, Tr. 2525; CX 479).

355. ESI also agreed, in its December 22, 1997 letter, to grant licenses to Schering for bupirone, enalapril, and three other products to be agreed upon. (Herman, Tr. 2528; CX 473; CX 1509 at 70 (Hoffman Dep.)). ESI countered with an initial \$ 5 million payment, to be followed by further payments upon the FDA's issuance of an approval letter for ESI's ANDA and thereafter for a total of \$ 55 million on an agreed-upon time schedule. (Hoffman, Tr. 2528; CX 473). This represents a \$ 50 million difference from Schering's offer. (Herman, Tr. 2528; CX 470; CX 473). ESI also proposed a royalty rate of 50 percent of gross profit for the licenses to Schering, as opposed to Schering's proposal of 5 percent of annual sales. (Herman, Tr. 2528-29; CX 473; CX 470).

3. Settlement agreement in principle

356. Between the time of the December 22, 1997 correspondence and January 23, 1998, the date Schering and ESI reached an agreement in principle, Schering and ESI had agreed on a January 1, 2004 date of entry for ESI. (Hoffman, Tr. 2640, 2619-20, 2638; CX 1509 at 70 (Hoffman Dep.); Herman, Tr. 2532-33). Schering told ESI that January 1, 2004 was as far as Schering would go. (CX 1482 at 99-100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.); CX 1492 at 136-37 (Dey I.H.)). Schering made it very clear to ESI that "that was it. That was as

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far as they would go, and there wouldn't be any further negotiating on that point." (CX 1482 at 99-100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.)).

357. The final mediation sessions occurred on January 22 and 23, 1998, in conjunction with a Markman hearing held on January 21 and 22, 1998. (Herman, Tr. 2529). A Markman hearing is a hearing at which evidence is taken and argument is heard so that the Court can interpret the claims of the patent at issue in the lawsuit. (Herman, Tr. 2529).

358. On January 22, 1998, the second day of the Markman hearing, the Court finished hearing evidence at around 1 p.m. (SPX 687, at ESI HRG 000126-27). The parties had another settlement conference with Judge Rueter scheduled for 2 p.m. (SPX 687, at ESI HRG 000126-27). The parties spent about three and a half hours in the January 22, 1998 settlement conference with Judge Rueter. (SPX 687, at ESI HRG 000128).

359. On January 23, 1998, the parties had another settlement conference with Judge Rueter. (Herman, Tr. 2529). The session concluded about 11:30 p.m., when an agreement in principle was reached. (Herman, Tr. 2529, 2531-32).

360. At the January 23, 1998 meeting, for Schering, were Mr. Herman and Ms. Susan Lee, Director of Patent Litigation. For ESI, were Mr. Heller and Dr. Dey. (Herman, Tr. 2532). During the evening, there were also calls between Judge Rueter and John Hoffman of Schering, who was at home, and between Judge Rueter and Mr. Driscoll, who was on his cellular phone at a New Jersey Nets basketball game with his sons. (Hoffman, Tr. 2603, 2618-19; 2629; Herman, Tr. 2532; Driscoll, Tr. 2706).

361. Before the January 23, 1998 mediation conference, the date of market entry for ESI's generic product had been agreed to in principle as January 1, 2004. (Hoffman, Tr. 2640, 2619-20, 2638; Herman, Tr. 2532-33). The parties had also agreed in principle that Schering would license generic enalapril and

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buspironone from ESI for \$ 15 million. (Herman, Tr. 2532; Hoffman, Tr. 2620).

362. During the meeting, ESI insisted on additional payments. (Herman, Tr. 2533). Mr. Herman took the position that Schering was not going to pay any more money, and that it wanted to try the case. (Herman, Tr. 2533). Schering eventually agreed to pay ESI \$ 5 million to settle the case. (Hoffman, Tr. 2620; Herman, Tr. 2534). ESI continued to insist on another \$ 10 million. (Herman, Tr. 2535).

363. Driscoll, testified that he came up with a concept under which Schering would not have to pay ESI any money if ESI could not obtain approval of its ANDA product. If ESI received approval for its ANDA by a date certain, Schering would make a certain payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21; CX 1492 at 156-57 (Dey I.H.)). If the date was later, it would be a lesser payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21). Driscoll ultimately agreed that Schering could make certain payments, consisting of \$ 10 million if ESI's ANDA were approved by July, \$ 5 million if it were approved 6 months later, with further decreasing payments. (Driscoll, Tr. 2712).

364. When Driscoll made this commitment, he believed that Schering would not have to pay it. (Driscoll, Tr. 2713, 2722; CX 1509 at 104 (Hoffman Dep.); CX 1482 at 109 (Alaburda I.H.)).

365. Judge Rueter asked the parties to write up the terms and initial or sign them that night. (Hoffman, Tr. 2621). In the secretarial area of Judge Rueter's chambers, Heller, counsel for ESI, hand wrote out the settlement principles with Schering's representatives. (Herman, Tr. 2537, 2488; CX 472).

366. The two-page handwritten agreement in principle, dated January 23, 1998, was signed by Mr. Heller, for ESI, and for Key by Ms. Susan Lee, who was the director of patent litigation for Schering. (Herman, Tr. 2488-89; CX 472).

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367. The January 23, 1998 handwritten agreement in principle states that Schering would grant ESI a license under its K-Dur patent beginning on January 1, 2004. (CX 472).

368. The January 23, 1998 handwritten agreement, states that ESI grants to Schering the right to market ESI's generic versions of enalapril and buspirone in Europe. (CX 472). The handwritten agreement also states that Schering would provide \$ 10 million to ESI upon the signing of the settlement agreement, and \$ 10 million split into equal monthly installments to be paid over seven and a half years. (CX 472). In addition, the handwritten agreement states that Schering would pay ESI an amount between \$ 625,000 and \$ 10 million, depending on the date of FDA approval of ESI's generic version of K-Dur 20. (CX 472).

369. Immediately after the agreement in principle was reached on January 23, 1998, the district judge conditionally dismissed the case. (Hoffman, Tr. 2651-52).

4. Final settlement agreement

370. Ms. Somerville, ESI's outside counsel, later sent a more formal draft agreement to Mr. Herman, accompanied by a transmittal letter. (Herman, Tr. 2538; CX 478). That initial draft does not accurately reflect what the parties agreed to that evening with Judge Rueter. (Herman, Tr. 2539; SPX 1266 at 181-82; CX 478). Paragraph 16 of the draft characterizes all the payments as royalty payments, when only \$ 15 million of the \$ 30 million were royalty payments. (Herman, Tr. 2539; CX 478).

371. This error was corrected in the final drafts of the agreements. (Herman, Tr. 2539; CX 479; CX 480). The final drafts of the agreements were prepared by Schering's outside counsel, Covington & Burling. (Herman, Tr. 2539). The final agreement was reached in June 1998. (Herman, Tr. 2539; Hoffman, Tr. 2652; CX 479).

372. Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a \$ 5 million noncontingent payment

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and an additional \$ 10 million contingent on ESI's FDA approval. (Hoffman, Tr. 2643; CX 479). Schering granted under the '743 patent a royalty free license to ESI effective, January 1, 2004. (Hoffman, Tr. 2643; CX 479).

373. The final settlement agreement also provides that Schering wishes to market in Europe certain pharmaceutical products for which ESI has filed ANDAs with the FDA. (CX 479).

374. As provided in the earlier handwritten agreement, Schering and ESI also entered into a contemporaneous license agreement, dated June 19, 1998, whereby AHP and ESI granted to Schering the licenses to enalapril and buspirone in exchange for \$ 15 million. The license agreement includes a statement that the parties desire to eliminate the uncertainties and costs of the patent litigation between Schering and ESI over the '743 patent. (CX 479).

375. Schering paid ESI \$ 5 million ten days after the execution and delivery of the June 19, 1998 final settlement agreement. (Schering Answer at P59). Shortly before the June 1999, \$ 10 million payment deadline, ESI received approval from the FDA. (Hoffman, Tr. 2646). Schering then paid ESI \$ 10 million. (Hoffman, Tr. 2646).

5. Settlement language related to other products

376. The terms of the final settlement agreement that were added after the agreement in principle was reached included: (1) ESI could not market any potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" until January 1, 2004; (2) ESI cannot market more than one new potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" between January 1, 2004 and September 5, 2006; (3) ESI cannot conduct, sponsor, file, or support a bioequivalence study or a substitutability study of a potassium chloride product to K-Dur 10 or K-Dur 20 until Schering's patent

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expires in 2006; (4) if ESI acquires a business, the new business could not seek FDA approval for a potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" prior to September 5, 2006; and (5) ESI cannot transfer ESI's ANDA. (CX 479).

377. The inclusion of clauses in the settlement agreements that affected ESI's exploitation of products similar to K-Dur 20 for a period of time prevent ESI from making minor, insubstantial modifications to its product and filing another ANDA with an infringing product. (SPX 1228 at 159-60 (Dey I.H.)).

6. Complaint Counsel did not prove that Schering's payment to ESI was a payment to delay entry

378. Complaint Counsel introduced fact evidence only in the form of deposition and investigational hearing testimony of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. It offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. (Bresnahan, Tr. 618-40).

379. Professor Bresnahan testified that to reach a conclusion that the agreement between Schering and ESI delayed competition, he relied upon what he characterized as an "assumption" that if ESI had won its patent suit, it might have been able to enter before March 2002. (Bresnahan, Tr. 620-21). This unfounded opinion, based only on speculation, does not demonstrate that the patent case would have settled any earlier for any reason.

380. Complaint Counsel offered insufficient evidence to show that the \$ 15 million was not paid for the licenses to enalapril and buspirone. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. Complaint Counsel offered insufficient evidence of what the fair value of enalapril and buspirone was.

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381. Schering has made no sales from either enalapril or buspirone. (Schering Answer at P56). Schering has been pursuing registration of both enalapril and buspirone in Europe and anticipates filing for approval in 2002. (SPX 1242 at 133-35 (Kapur Dep.)).

382. A statement made in an investigational hearing by Michael Dey, an ESI official involved in the settlement negotiations, that "if Schering had been willing to allow [ESI] onto the market before 2004," ESI "may have" been willing to settle for less money is insufficient to demonstrate that Schering paid ESI only for delay or that the case would have settled sooner for any reason. (Bresnahan, Tr. 632-33 (quoting Dey I.H.)). This is not sufficient to prove payment only for delay.

383. Complaint Counsel offered insufficient evidence to demonstrate that the patent case would have settled without the provision for the product license.

384. Schering's expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. (Mnookin, Tr. 2675-76.) Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. (Mnookin, Tr. 2675-76.)

I. Whether Schering's Payments to Upsher-Smith and AHP Were for Delay

385. A patent owner is given the exclusive right to preclude others from making, selling, using or vending the subject matter of the invention covered by the claim. (35 U.S.C. § 271(a); Miller, Tr. 3310-11). To enforce a patent, the patentee is given the right to sue in a federal court for patent infringement. (35 U.S.C. § 271; 28 U.S.C. § 1338; Miller, Tr. 3316).

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386. The '743 patent gives Schering the right to "exclude others from making, using, offering for sale, and selling the invention throughout the United States," together with certain additional rights provided in the statute. 35 U.S.C. § 154. The '743 patent expires on September 5, 2006. (Miller, Tr. 3311; SPX 1275 at P8). Hence, Schering has the right to exclude infringing products from the market until September 5, 2006. (Miller, Tr. 3311).

387. An applicant who has filed an ANDA with a Paragraph IV certification must notify the branded drug manufacturer and the patent holder of the filing of its ANDA, and provide a detailed statement of the factual and legal bases for the ANDA filer's opinion that the patents will not be infringed or are invalid. (21 U.S.C. § 355 (j)(2)(B)(i) and (ii); Hoffman, Tr. 2217-18).

388. Under Hatch-Waxman, the branded drug manufacturer has 45 days after receiving such notice to file a patent infringement suit against the ANDA applicant in order to automatically trigger a stay of FDA approval of the ANDA. If a patent infringement suit is filed within this 45-day window, the FDA cannot give final approval for the ANDA until the earliest of: (1) the date the patent is judicially determined to be invalid or not infringed; (2) a judicial determination of the patent litigation, or (3) the expiration of an automatic 30-month waiting period, which may be extended or shortened by the court. (Hoffman, Tr. 2218; Rosenthal, Tr. 1575-76; 21 U.S.C. § 355 (j)(5)(B)(iii)).

389. The patent holder, if successful in proving that the generic product infringes his patent in the patent infringement litigation, can keep the ANDA from being approved and enjoin the marketing of the generic product until the patent expires. (Miller, Tr. 3316-17; Rosenthal, Tr. 1576).

390. A generic drug company could be involved in patent litigation with the patent holder, and at the end of the 30-month stay of FDA approval receive final approval from the FDA for its product, but still not enter the market given the risks of patent infringement and potential treble damages. (Rosenthal, Tr. 1578-81). There are numerous situations in which companies have not

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gone to market with their generic alternatives, even though they have FDA approval, specifically out of fear of an adverse ruling in an ongoing patent infringement suit. (Rosenthal, Tr. 1582-87; Kerr, Tr. 6259-60; 6901-02).

391. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20. (Drilsas, Tr. 4902-03). Shortly before June 1999, ESI received approval from the FDA for its generic version of K-Dur 20. (Hoffman, Tr. 2646). However, it would be "foolhardy" for a generic to enter the market while patent litigation is pending because of the potential "very, very severe penalties." Kerr, Tr. 6738. Paul Kralovec, Upsher-Smith's CFO, testified that for Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "financial suicide." (Kralovec, Tr. 5038). ("If we had lost the case, it could have been significant financial obligation for us to pay as far as damages go."). Schering's lead counsel on the patent infringement case brought by Key Pharmaceuticals against ESI Lederle, Anthony Herman, a partner at the law firm of Covington & Burling, testified that in his practice he has never encountered a generic manufacturer who sought to enter the market after the 30-month stay had expired but while patent litigation was ongoing. (Herman, Tr. 2484-2568).

392. Thus, even though Upsher-Smith and ESI had final FDA approval as of November 1998 and June 1999 respectively, it is highly unlikely that either would have marketed on those dates while patent litigation was still pending. (F. 391).

393. There is no way to determine the date or the outcome of the judicial determination of the patent litigation. Schering's expert, Mr. James O'Shaughnessy, a patent trial lawyer testified that patent litigation is by its very nature unpredictable. (CCPTB at p. 71; Miller, Tr. 7065). Schering's patent expert, Mr. Charles Miller testified there is no recognized methodology for handicapping trials or for testing the reliability of predictions of litigation outcomes. (CCPTB at p. 73; Miller, Tr. 3296). Opinions

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on the merits of cases that settle before the court decides them can never be tested. (CCPTB at p. 73; Miller, Tr. 3296).

394. Complaint Counsel acknowledges that the outcome of the patent litigation cannot be predicted. (CCPTB at p. 71). Complaint counsel's patent litigation expert, Professor Martin Adelman, testified that patent infringement cases can take up to five years to litigate in some federal district courts, not including appeals. (Adelman, Tr. 7773-74). Intellectual property litigation is more uncertain than other types of litigation. The Federal Circuit, which hears intellectual property appeals, has a 50 percent reversal rate, making it extremely difficult to predict the outcomes of intellectual property litigation. (O'Shaughnessy, Tr. 7065-66).

J. 180 Day Exclusivity Period

1. No firm was actually blocked from introducing a generic 20 mEq potassium chloride supplement

395. Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx testified that Andrx **[redacted]** (Rosenthal, Tr. 1553, 1591, 1734-35). **[redacted]** (Rosenthal, Tr. 1728-31). **[redacted]** (Rosenthal, Tr. 1735).

396. Executives at Upsher-Smith were not aware of any other potential competitors blocked from the market. (Dritsas, Tr. 4667, 4686-87; Troup, Tr. 5494-95).

397. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. (Bresnahan, Tr. 912). Despite the running of the 180-day period, Bresnahan admitted that there were currently three generic 20 mEq potassium tablet products on the market during the period; Warrick (Schering), Klor Con M20 (Upsher-Smith), and Qualitest. (Bresnahan, Tr. 929). Bresnahan also testified that the change in law regarding 180-day exclusivity was not attributable to Upsher-Smith's or Schering's conduct. (Bresnahan, Tr. 982).

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398. Complaint Counsel introduced no evidence of any competitor blocked from entry into the market because of Upsher-Smith's 180 exclusivity.

2. The 180-day period was not discussed between Schering-Plough and Upsher Smith

399. The 180-day exclusivity period was never discussed during settlement negotiations between Schering Plough and Upsher-Smith. (Troup, Tr. 5492-93; Hoffman, Tr. 3550-51). Nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. (Bresnahan, Tr. 914-17); CX 348; Troup, Tr. 5493).

K. Monopolization

1. Market share

400. In March 1995, seventy-one percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1275; CX 13 at SP 003044). In April 1996, sixty-eight percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1276-1277; CX 746, CX 18). Of total prescriptions between 1994 and 1999, the total number of K-Dur 20 prescriptions was only slightly higher than the total number of generic prescriptions, with K-Dur 20 comprising 25.7% versus the generics' 24.1% (1994); K-Dur 20's 28.4% versus the generics' 27.4% (1995); K-Dur 20's 30.9% versus the generics' 28.9% (1996); K-Dur 20's 33.0% versus the generics' 31.1% (1997); K-Dur 20's 34.8% versus the generics' 32.7% (1998); and K-Dur 20's 35.8% versus the generics 33.6% (1999). (CX 1389 at SP 23 00016).

401. As reflected in a July 1, 1996 Schering document entitled "K-Dur Marketing Research Backgrounder," K-Dur 20 represented 32 percent of total prescriptions. (CX 746 at SP 2300382). The 1998 K-Dur Marketing Plan represents that the

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market share for K-Dur 20 as of August 1997 was less than 38 percent. (Bresnahan, Tr. 1279; CX 747 at SP 23 00091).

402. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. CX 62 at SP 089326 for 1997 generic KCL growth. However, at the time relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. (CX 62 at 089327). With K-Dur 20 at 33.0% of total potassium chloride prescriptions, id., other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. (Russo, Tr. 3421-2212).

403. Between 1995 and 1999, other Schering documents calculated the market share of K-Dur 20 at between 30 and 40 percent. (Bresnahan, Tr. 1169-70). No Schering documents gave Schering a 100% market share.

404. Schering's market share does not indicate that Schering had monopoly power. (Addanki, Tr. 5719, 5724, 6209; Bresnahan, Tr. 876).

2. Lack of entry barriers and the ability of rivals to expand output

405. Professor Bresnahan did not analyze entry into potassium chloride supplements by Ethex, Apothecon, ESI Lederle, Medeva or Biocraft in 1996 as part of his economic analysis in this case. (Bresnahan, Tr. 8185). Professor Bresnahan did not analyze how long it took these firms to begin selling potassium chloride. [Bresnahan, Tr. 8185-86].

406. As of 1997, there were over 30 products competing in the potassium chloride market, all of which had entered at some point. (Addanki, Tr. 5721-22). A number of new competitors

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entered the market in recent years. (Addanki, Tr. 5721; Dritsas, Tr. 4715). Several companies entered the potassium chloride market in 1996, including Apothecon, ESI, Medeva and Biocraft. (Dritsas, Tr. 4717; USX 626; USL 15228). Apothecon in particular was a very low-priced competitor with a wide range of generic products, including 10 mEq potassium product. (Dritsas, Tr. 4717-18). There were at least two other products that had already been approved, K-Norm and K-Lease, that could enter the market, but which were not yet in the market. (CX 4 at 184403).

407. Firms already in the market could expand output. (Addanki, Tr. 5722-23). Apothecon's 10 mEq market grew 80 percent in 1998, which was a significant shift in sales of potassium chloride. (Addanki, Tr. 6177; CX 75 at USL 142364; CX 73 at USL 143202-03). In 1999, Ethex and Major increased their 10 mEq potassium chloride capsule sales revenue by 68.4 and 19.7 percent, respectively, and increased unit output by 56.6 and 6.1 percent, respectively. (CX 76 at 162110). Among 10 mEq wax matrix producers, K-Tab, Qualitest, Major and Apothecon increased unit sales by 17, 100, 51 and 60 percent, respectively. (CX 76 at 162109; Addanki, Tr. 6181; USL at 162109). Another product, Slow-K, showed a unit increase of 41% from 1994 to 1995. (Addanki, Tr. 6181; USX 380).

408. Complaint Counsel presented no evidence that Schering had any ability to restrict the output of the more than 20 firms selling therapeutically equivalent potassium chloride supplements.

3. Sales of K-Dur were expanding

409. Schering's documents reflect that Schering was seeking to expand sales and to engage in advertising and promotional activities that stimulate demand for the product. (Addanki, Tr. 5744). Such activities have the effect of expanding output. (Addanki, Tr. 5744). Dr. Addanki analyzed Schering's output as part of his analysis of whether Schering had monopoly power. (Addanki, Tr. 5744).

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410. Schering's sales of K-Dur 20 did expand. From 1990-1996, K-Dur 20 grew more rapidly in units than did the rest of the potassium chloride market. (CX 79 at USL 138066). Schering's sales continued to expand between 1996 and 2000. (Bresnahan, Tr. 8181). According to Professor Bresnahan, between 1997 and 2001, K-Dur output increased by one-quarter (25 percent). (Bresnahan, Tr. 8181).

411. Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and physician awareness activities. Addanki, Tr. 5726-28. Schering outspent Upsher-Smith in its marketing of Klor Con 10 by a factor of 100 to 1. (Bresnahan, Tr. 734). (CX 746 at 00384 (Appendix A-5, K-Dur Marketing Research Background, July 1, 1996). This extensive advertising campaign was designed to compete against generic forms of potassium supplements. (Addanki, Tr. 5730-32).

412. Schering invested millions in promotion and field force effort, with a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed K-Dur 10 and K-Dur 20. (Russo, Tr. 3418-19, 3425-26).

413. Schering's executives recognized that marketing was a key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039).

4. Bresnahan's conclusion that K-Dur 20 was a monopoly was not based on a thorough examination of the potassium supplement industry

414. Complaint Counsel's economic expert, Professor Bresnahan opined that Schering has monopoly power in the K-Dur 20 market. Under Professor Bresnahan's test, the issue of whether or not the June 1997 Settlement Agreement of the '743

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patent infringement case was "anticompetitive" turns on the following three questions:

- (1) Does the patent holder have monopoly power?
- (2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
- (3) Is there a payment to the potential entrant to delay its entry? The payment can take any form, as long as it is a not positive value to the entrant.

Bresnahan, Tr. 655-58.

415. The three elements of the Bresnahan Test are to be assessed as of the date the Agreement was entered into, June 17, 1997. Bresnahan, Tr. 659.

416. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. Bresnahan, Tr. 660-661.

417. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. Bresnahan, Tr. 419 ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't wouldn't do anything to harm competition.").

418. Professor Bresnahan incorrectly determined that Schering had unlawful monopoly power. (F. 30).

419. Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for its Klor Con 10 or Klor Con 8 potassium products, or the pricing of other potassium manufacturers' potassium products because he did not have access to a data set of such pricing data for the period 1995 to 2001. (Bresnahan, Tr. 834-35).

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420. Bresnahan did not calculate the pricing differential (if any) between the various firms' potassium products and the price charged by Schering for equivalent doses of K-Dur 20. (Bresnahan, Tr. 1071; USX 72).

421. Bresnahan conducted no econometric analyses comparing sales of 10 mEq tablets with sales of 20 mEq tablets or comparing the sales of 20 mEq potassium powders with 20 mEq tablets. (Bresnahan, Tr. 685-89).

422. Bresnahan did not study the cross-elasticity of demand between K-Dur 20 and other products. (Bresnahan, Tr. 810-11). Bresnahan did not study the direct price elasticity between K-Dur 20 and other potassium products.

423. Bresnahan did not attempt a study of the costs of Schering's K-Dur 20 products or the relationship between Schering's costs for producing K-Dur 20 and the price Schering charged for K-Dur 20. (Bresnahan, Tr. 834, 1274, 1003, 8148-50).

424. Bresnahan did not study the level of rebates that Schering gave back to its customers who purchased K-Dur 20 potassium products in 1995, 1996 or 1997. (Bresnahan, Tr. 702). Bresnahan conceded that there was significant promotional spending by Schering to promote its K-Dur 20 product, but he did not study this spending. (Bresnahan, Tr. 651-52, 735, 763, 1176).

425. Bresnahan did not make any formal study of the impact of Schering-Plough's marketing on the total market demand for potassium chloride products. (Bresnahan, Tr. 651-52).

426. Bresnahan did not study "first mover effects," the effects of being the first to sell a particular product of K-Dur 20. (Bresnahan, Tr. 653).

427. Bresnahan made no analysis of promotional expenditures by Schering on K-Dur 20 in his report. (Bresnahan, Tr. 734-35). But Bresnahan acknowledged that Schering outspent Micro-K in by a factor of ten to one and outspent Upsher-Smith in its

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marketing of Klor Con 10 by a factor of 100 to one. (Bresnahan, Tr. 734.)

428. Bresnahan had no access to monthly sales data or pricing data from any firm aside from Respondents. (Bresnahan, Tr. 867-68).

429. Bresnahan did not review any marketing documents from other potassium supplement manufacturers. (Bresnahan, Tr. 867). Bresnahan did not systematically evaluate the levels of promotional spending by other potassium supplement firms over the period 1997 to 2001, such as the manufacturers of the branded potassium products Micro-K, Slow K, K-Tab. (Bresnahan, Tr. 8134).

430. Professor Bresnahan was unaware of clinical trials that compare patient compliance attributes of taking two 10 mEq tablets versus one 20 mEq tablet. (Bresnahan, Tr. 692).

431. Bresnahan did not evaluate or analyze the fact that four firms entered the U.S. potassium chloride market in 1996. (Bresnahan, Tr. 8184-85).

III. CONCLUSIONS OF LAW AND ANALYSIS

A. Jurisdiction

The Complaint charges Schering and Upsher-Smith ("Respondents") with violations of Section 5 of the FTC Act. 15 U.S.C. § 45. Section 5 of the FTC Act gives the Commission jurisdiction to prevent unfair methods of competition by "persons, partnerships, or corporations." 15 U.S.C. § 45. Schering and Upsher-Smith are corporations engaged in the interstate sale of pharmaceutical products. F. 1-9. The Commission has jurisdiction over acts or practices "in or affecting commerce," providing that their effect on commerce is substantial. *McLain v. Real Estate Bd. of New Orleans, Inc.*, 444 U.S. 232, 241-42 (1980); *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 745-46 (1976). Respondents' challenged activities relating to the sale of 20 mEq

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potassium supplements have an obvious nexus to interstate commerce. F. 1-9. Accordingly, the Commission has jurisdiction over Respondents and the subject matter of this proceeding.

B. Burden of Proof

An initial decision must be supported by "reliable, probative and substantive evidence." Commission Rule 3.51(c), 16 C.F.R. § 3.51(c)(1). "Substantial evidence is more than a mere scintilla. It means such evidence as a reasonable mind would accept as adequate to support a conclusion. It must be of such character as to afford a substantial basis of fact from which the fact in issue can be reasonably inferred. It excludes vague, uncertain or irrelevant matter. It implies a quality and character of proof which induces conviction and makes a lasting impression on reason." *Carlay Co. v. FTC*, 153 F.2d 493, 496 (7th Cir. 1946).

"Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." Commission Rule 3.43(a), 16 C.F.R. § 3.43(a). This is consistent with Section 556(d) of the Administrative Procedure Act ("APA"): "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). Further, under the APA, an order may not be issued "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); see also *In re Standard Oil Co. of California*, 84 F.T.C. 1401, 1446-47 (1974) (finding that under the APA, "complaint counsel have failed to satisfy their burden to establish by 'reliable, probative and substantial evidence' that the results mentioned in the preceding findings do not support [respondent's] advertising claims").

"The antitrust plaintiff must present evidence sufficient to carry its burden of proving that there was [an anticompetitive] agreement." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 763 (1984). The government bears the burden of establishing

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a violation of antitrust law. *United States v. E.I. duPont de Nemours & Co.*, 366 U.S. 316, 334 (1961).

C. Statutory and Regulatory Framework

As set forth in the findings of fact, this case arises from the agreements to settle patent infringement suits brought by Schering, as the manufacturer of the brand name drug K-Dur 20, protected by the '743 patent, against Upsher-Smith and against ESI, as manufacturers of generic drugs, each of which had filed an Abbreviated New Drug Application ("ANDA") with the FDA that contained a Paragraph IV certification that the '743 patent was invalid or not infringed. In order to fully understand the issues involved herein, an overview of the statutory and regulatory framework from which the challenged agreements arose is necessary.

1. Patent Law

Article 1, Section 8, Clause 8 of the U.S. Constitution empowers Congress "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others--for example, by the initiation of infringement litigation from manufacturing, using and/or selling the invention during the patent term. See 35 U.S.C. §§ 101, 154, 271, 281. (The "Patent Act," 35 U.S.C. §§ 1 et seq.). The Patent Act also expressly provides that a patent is assignable: the patent owner may "grant and convey an exclusive right under his application for patent . . . to the whole or any specified part of the United States." 35 U.S.C. § 261.

The exclusive rights provided for in patent laws are intended to offer an incentive for investors to take risks in performing research and development. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81, 484 (1974); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229-30 (1964). The Federal Trade

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Commission recognizes the role of intellectual property laws in promoting innovation and enhancing consumer welfare.

The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without competitors. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers.

U.S. Dep't of Justice and Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property § 1.0 (1995), reprinted in 4 Trade Reg. Rep. (CCH) P13,132, at 20,734. The role of patent law in interpreting claims brought under antitrust law is discussed more fully in Section F.4.b. *infra*.

2. The Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, authorizes the Food and Drug Administration ("FDA") to regulate the marketing and sale of drugs in the United States. 21 U.S.C. § § 301-397.

An applicant seeking to market a new brand-name drug usually must prepare a New Drug Application ("NDA") for FDA consideration. 21 U.S.C. § 355. Preparing an NDA is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy. F.13; *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001). The NDA must also include a list of patents which claim the drug. 21 U.S.C. § 355(b)(1). If the FDA approves the NDA, it publishes a listing of the drug and patents on the drug's approved aspects in Approved Drug

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Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, which simplified the procedure for obtaining approval of generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355. Under the Hatch-Waxman Act, manufacturers of generic drugs are required to submit an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA offers an expedited approval process for generic drug manufacturers. *Mylan Pharmaceuticals*, 268 F.3d at 1325. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. 21 U.S.C. § 355(j)(2)(A).

When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patent must certify that the patent on the brand name drug is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. 21 U.S.C. § § 355(j)(2)(A)(vii)(I) to (IV). This is known as a "Paragraph IV Certification." If the ANDA contains a Paragraph IV certification, the ANDA applicant must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. 21 U.S.C. § 355(j)(2)(B)(i). Upon receiving notice of a Paragraph IV certification, the patent holder has 45 days in which to file a patent infringement suit against the generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iii). If a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period. 21 U.S.C. § 355(j)(5)(B)(iii).

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The statutory framework of the Hatch-Waxman Act creates the potential for costly patent litigation against the generic maker that files a Paragraph IV-certified ANDA. *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1, 7 (D.D.C. 2001), rev'd on other grounds, 268 F.3d 1323, 1325 (Fed. Cir. 2001). As an incentive to the first generic maker to expose itself to the risk of costly patent litigation, Hatch-Waxman provides that the first to file a Paragraph-IV certified ANDA ("the first filer") is eligible for a 180 day period of exclusivity ("the 180 day Exclusivity Period"). *Id.*; 21 U.S.C. § 355(j)(5)(B)(iv). That is, during those 180 days, the FDA will not approve any other ANDA for the same generic product until the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patent claiming the brand name drug are invalid or not infringed. *Mylan*, 139 F. Supp. 2d at 7; 21 U.S.C. § 355(j)(5)(B)(iv).

The provisions of the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds). Thus, although the declared purpose of this legislation was to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962[.]" H.R. Rep. No. 98-857, pt. 1 at 14 (1984), 1984 U.S.C.C.A.N. 2647, Congress expressly recognized the importance of patents.

Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

H.R. Rep. No. 98-857, pt. 1 at 17, 1984 U.S.C.C.A.N. at 2650.

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Hatch-Waxman does not compel the holder of a valid patent to relinquish the rights it holds pursuant to that patent prior to the expiration date of that patent.

D. Relevant Geographic and Product Market

The determination of the relevant market is essential to all four violations alleged in the Complaint. Violations One and Two of the Complaint allege that the agreements entered into between Schering and Upsher-Smith and between Schering and AHP (ESI) unreasonably restrained commerce. Complaint P68, 69.

Establishing the relevant market is the starting point in a rule of reason case. *California Dental Ass'n v. FTC*, 224 F.3d 942, 952 (9th Cir. 2000) (proof of relevant geographic and product market necessary for proving injury to competition in rule of reason case); *Stratmore v. Goodbody*, 866 F.2d 189, 194 (6th Cir. 1989) ("The starting point in a rule of reason case is to identify the relevant product and geographic markets."). See also *Twin City Sportservice, Inc. v. Finley & Co., Inc.*, 676 F.2d 1291, 1300 (9th Cir. 1982) ("It is also worth noting that the effort to find a relevant market in this litigation was not performed without purpose. A definition of a relevant market was necessary in order to assess possible Sherman Act violations."). The plaintiff bears the burden of proof of defining the relevant market. *Brokerage Concepts v. U.S. Healthcare, Inc.*, 140 F.3d 494, 513 (3rd Cir. 1998) ("The burden is on the plaintiff to define both components [geographic and product] of the relevant market."); *Double D Spotting Serv. v. Supervalu, Inc.*, 136 F.3d 554, 560 (8th Cir. 1998). As discussed in Section E.4, *infra*, rule of reason analysis is required in this case.

Determination of relevant product market is an especially important inquiry here, where Complaint Counsel's proof that the agreements are anticompetitive is based on a finding that Schering had monopoly power. Complaint Counsel's economic expert, Professor Bresnahan, used a three-part test to determine whether the patent settlements between Schering and Upsher-Smith and between Schering and AHP (ESI) were anticompetitive. F. 414. The three-part test asks:

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- (1) Does the patent holder have monopoly power?
- (2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
- (3) Is there a payment to the potential entrant to delay its entry? The payment can take any form, as long as it is a net positive value to the entrant.

F. 414. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. F. 415-16. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. F. 414. ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't--wouldn't do anything to harm competition."). By making monopoly power an integral part of that expert's testimony, a determination of relevant market is an integral part of Complaint Counsel's case.

In its post trial briefs, Complaint Counsel suggests that it need not delineate the relevant product market. Complaint Counsel asserts that direct evidence of anticompetitive effects "obviates the need, as a matter of law, to undertake the market definition exercise respondents advance." Complaint Counsel's Post Trial Brief ("CCPTB") at 47. Complaint Counsel argues that the Supreme Court "in *FTC v. Indiana Fed'n of Dentists* . . . made clear that proof of actual anticompetitive effects make market definition and market power inquiries unnecessary." CCPTB at 83. However, *Indiana Fed'n of Dentists* does not relieve Complaint Counsel of its obligation to define the relevant market. Rather, *Indiana Fed'n of Dentists* holds that proof of actual detrimental effects can obviate the need for an inquiry into market power. *FTC v. Indiana Fed'n of Dentists* 476 U.S. 447, 460-61 (1986). Complaint Counsel further relies on *Toys "R" Us, Inc. v. FTC*, which holds that, "in a properly defined relevant market," direct evidence of anticompetitive effects is one way to prove market power. 221

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F.3d 928, 937 (7th Cir. 2000). Thus, while Toys R' Us may relieve Complaint Counsel of proving market power, it does not relieve Complaint Counsel from properly defining the market.

Further, Complaint Counsel's suggestion that, because it has presented evidence of anticompetitive effects, it need not present evidence of monopoly power is illogical. Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected.

Moreover, Complaint Counsel's position that it need not prove or define the relevant market clearly undermines the theory and opinions of Complaint Counsel's expert witness, as his test is premised on finding a monopoly and a threat to the monopoly. See CX 1590 (the "three pies" chart); F. 414-16 (if Schering was not a "monopolist" then the Bresnahan Test is not satisfied for anticompetitive agreements).

To prove that the agreements did have anticompetitive effects, Complaint Counsel relied on the testimony of Professor Bresnahan who reached this conclusion based on his finding that Schering was a monopoly and had market power. Without a proper market definition, Bresnahan's opinions are without proper foundation and lose credibility. The case that was brought involved proof of a relevant product market and the expert premised his analysis on the proof of a monopolist within a relevant product market. Accordingly, Complaint Counsel's proof was not built upon a proper determination of market power or monopoly power.

Violations Three and Four of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and AHP to monopolize the relevant markets. Complaint P70, 71. Establishing the relevant market is also necessary to assess whether a defendant possesses monopoly power. *Spectrum Sports, Inc., v. McQuillan*, 506 U.S.

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447, 455-56 (1993) (to establish monopolization or attempted monopolization it is "necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.") (citations omitted); *Walker Process Equip. Inc., v. Food Mach. and Chem. Corp.*, 382 U.S. 172, 177 (1965) ("Without a definition of that market there is no way to measure [the respondent's] ability to lessen or destroy competition.").

Complaint Counsel bears the burden to establish the relevant market, which is "an indispensable element of any monopolization case." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1355 (Fed Cir. 1999); see *Elliot v. United Ctr.*, 126 F.3d 1003, 1003-04 (7th Cir. 1997); *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 781 (5th Cir. 1999); *H.J., Inc. v. Int'l Tel. & Tel.*, 867 F.2d 1531, 1537 (8th Cir. 1989) ("The plaintiff carries the burden of describing a well-defined relevant market, both geographically and by product, which the defendants monopolized."). Complaint Counsel did not meet its burden of establishing the relevant product market.

1. Geographic Market

The relevant geographic market is the region "in which the seller operates, and to which the purchaser can practicably turn for supplies." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961). Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose products have been approved for sale in the United States by the FDA. F. 26. Schering and Upsher-Smith have FDA approval and do sell their potassium chloride supplements in the United States. F. 25-28. Therefore, the relevant geographic market for assessing the allegations of the Complaint is the United States. F. 25-28

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2. Product Market

The Complaint alleges:

The relevant markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

Complaint P21. At trial, Complaint Counsel's position was that the relevant product market is 20 milliequivalent potassium chloride tablets and capsules. F. 30.

Respondents argue that the evidence does not support Complaint Counsel's alleged product market of 20 mEq sustained release potassium chloride tablets.

The greater weight of credible evidence shows that the relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. F. 29-118.

a. Functional interchangeability of potassium supplements

The relevant market for purposes of antitrust litigation is the "area of effective competition" within which the defendant operates. *Tampa Elec.*, 365 U.S. at 327-28. As the Supreme Court explained in *E.I. du Pont Nemours*:

The 'market' which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The tests are constant. The market is composed of products that have reasonable interchangeability for the

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purposes for which they are produced--price, use and qualities considered.

351 U.S. at 404.

In defining a relevant product market, courts look to determine if products are "reasonably interchangeable." Courts consistently look to reasonable interchangeability as the primary indicator of a product market. See *United States v. Continental Can Co.*, 378 U.S. 441, 453-57 (1964) (glass jars and metal cans sufficiently interchangeable to be in the same market); *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 722, 726 (3d Cir. 1991) (relevant product market consisted of "Ford and other comparable tractors" based on reasonable interchangeability); *Kaiser Aluminum & Chem. Corp. v. F.T.C.*, 652 F.2d 1324, 1330 (7th Cir. 1981) ("the clearest indication that products should be included in the same market is if they are actually used by consumers in a readily interchangeable manner"); *F.T.C. v. R.R. Donnelley & Sons Co.*, 1990-2 Trade Cas. (CHH) P69,239 at 64,854-55 (D.D.C. 1990) (offset and gravure print processes interchangeable and in the same product market); *In re Liggett & Myers, Inc.*, 87 F.T.C. 1074, 1163 (1976) (premium and economy dog food found to be in the same market in view of interchangeability of use). See also *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) ("The pharmaceutical market is fundamentally different from the market for other products. In the pharmaceutical industry, there is a government-assured complete interchangeability of drug products.").

The first step in determining interchangeability of potassium supplements is to determine who makes the selection regarding which potassium supplement to be used. Potassium supplements are given by doctors to hypertensive patients to treat or prevent hypokalemia, a lack of potassium caused by the use of diuretic medications. F. 38. The doctor is the most important link in the chain of those involved in the decision of which potassium supplement to prescribe, F. 38, 118. The doctor diagnoses that a potassium supplement is required for the patient. F. 38, 118. The doctor is the one who is knowledgeable about what

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products/drugs are available to meet the patient's needs. Professor Bresnahan acknowledged that the demand for potassium begins with a patient presenting himself/herself to a doctor and receiving a potassium supplement prescription. F. 38, 118.

There is insufficient evidence to show that the patient has any control over this decision. After the doctor makes the diagnosis and writes the prescription, the pharmacy fills that prescription. F. 39, 118. The patient and/or medical insurance pay for the prescription. The credible evidence demonstrates that the pharmacist has little or no control over which potassium supplement product to dispense. In many states, the law allows no change. In some states, a generic may be substituted. F. 22-23. Thus, between the doctor, the pharmacist, and the patient, it is the doctor who exercises most, if not all, control over which potassium supplement product is selected for any given patient. Accordingly, the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor.

In 1997, more than 25 firms sold potassium supplements, including Schering-Plough and Upsher-Smith. F. 31-37. All forms of potassium are considered to be therapeutically equivalent; they all deliver potassium. F. 43-48. The high degree of interchangeability between various potassium products, including 20 mEq sustained-release products, was confirmed by Complaint Counsel's fact witnesses, Dean Goldberg and Russell Teagarden. F. 49-55.

Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. F. 50. Goldberg further testified that most, if not all, potassium chloride products are therapeutically equivalent. F. 50. Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. F. 50.

Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM"), testified

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that there is no separate listing for 20 mEq potassium chloride products on its formulary. F. 51-54. If Merck-Medco and other PBMs thought that unique characteristics existed that warrant a separate market for just 20 mEq sustained release potassium chloride products, there would be a separate classification on Merck-Medco's formulary. F. 51-54. He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medco did not even list K-Dur 20 as a prescription drug on its formulary. F. 51-54. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmaceutical companies. F. 51.

In addition, Professor Bresnahan conceded that K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-Lyte, Klotrix, Apothecon KCI and Ethex potassium chloride were all prescribed for the same "purpose" of treating potassium deficiency. F. 87.

The evidence demonstrates that many types of potassium supplements are interchangeable with K-Dur 20. Accordingly, because there are many other acceptable potassium supplements which may be substituted, the relevant market is not limited to 20 mEq potassium supplements.

b. Pricing of potassium supplements

Complaint Counsel has taken the position that the proper inquiry to determine the relevant market is not whether the products are functionally interchangeable, but whether the products constrained each other's prices. CCPTB at 85-86. Complaint Counsel relies on *In re Coca-Colu Bottling Co. of the Southwest*, which held that the relevant inquiry in conducting an antitrust analysis is not whether "certain [products] competed against each other in a broad sense," but instead whether such "products were sufficiently substitutable that they could constrain" each other's pricing. 118 F.T.C. 452, 541-42 (1994). *Coca-Cola Bottling* was a merger case with an overriding focus on the combined power to influence the market which would be wielded by the proposed merger partners. In addition, as stated below, *Coca-Cola Bottling* cited *Brown Shoe* with approval. *Id.*

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The Commission has not limited the inquiry to whether certain products are sufficiently substitutable that they could constrain each others products. E.g., *Int'l Assoc. of Conference Interpreters*, 123 F.T.C. 465, 640 (1997) (Section 2 case) (the Commission generally examines what products are reasonable substitutes for one another through a consideration of price, use and qualities). Moreover, in the context of prescription of drugs, the Commission in, *In re Warner Lambert Co.*, 87 F.T.C. 812, 877 (1976), found that branded and unbranded thyroid products constituted a single product market despite "lack of price elasticity."

Complaint Counsel cites to numerous cases for the assertion that a price difference can lead to a finding of a separate product market. CCPTB at 85 and 86 n.33. But these cases utilize the Supreme Court's *Brown Shoe* analysis and virtually always consider other *Brown Shoe* factors such as special characteristics, industry recognition, distinct customers, and other *Brown Shoe* "practical indicia." See *FTC v. Staples*, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997) (extensive reliance on *Brown Shoe* "practical indicia" for product market, including special characteristics of office superstores, industry recognition, extensive evidence of cross-elasticity of demand); *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 45 (D.D.C. 1998) (relies on *Brown Shoe*, in particular unique features of the drug wholesaling industry, including specialized customers such as hospitals dependent on wholesalers, to find a distinct product market; merger case); *Coca-Cola*, 118 F.T.C. at 541-42 (citing *Brown Shoe* with approval and conducting extensive review of sales channel differences between home market and cold drink market); *In re Olin Corp.*, 113 F.T.C. 400, 603 (1990) (liquid chlorine pool bleach in separate market from dry pool sanitizer where "physical and technical characteristics" differed; chemical concentration of active ingredient, chlorine, differed; shelf life differed; and customers were geographically distinct and functionally distinct pool service companies vs. homeowners).

The pharmaceutical industry case Complaint Counsel cites, *Smith-Kline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), found cephalosporin antibiotics to be a distinct product

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market from other antibiotics not because of price difference, but because, applying *Brown Shoe*, the Third Circuit found cephalosporins had special characteristics. Cephalosporins were (a) broad spectrum antibiotics "effective against a wider range of infectious organisms than are other antibiotics;" *id.* at 1064; ("cephalosporins are effective against the organism [ILLEGIBLE WORD]" staphylococci and gram negative bacilli, as contrasted with penicillins that "tend to be active against one but not the other"); (b) used for specialized patients: "cephalosporins are generally used in treating penicillin-allergic patients," *id.* at 1064; and (c) were "less toxic" than some other anti-infectives. *Id.* These "sufficiently unique features" are not present here where *K-Dur 20* and other potassium chloride products contain precisely the same therapeutic agent and are "therapeutically equivalent."

c. Complaint Counsel did not prove a single brand market

Although Complaint Counsel claims it does not have to prove relevant market, Complaint Counsel alleges that Schering had market power and a monopoly in the market for 20 mEq potassium supplement. However, at all times relevant, Schering had a valid patent for the 20 mEq potassium supplement. Therefore any monopolization or market power existed by virtue of the '743 patent. See *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984) (When the government has granted the seller "a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.")

d. Complaint Counsel did not present pricing data to support an Indiana Federation of Dentists analysis

Complaint Counsel cites to *Indiana Fed'n of Dentists*, 476 U.S. at 460-61, to show that "proof of actual detrimental effects . . . can obviate" the need for an inquiry into market power. CCPTB at 83. However, as discussed *infra*, the pricing evidence offered by Complaint Counsel's expert is inadequate in many respects and does not support an *Indiana Federation* analysis.

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Complaint Counsel's expert Professor Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for Klor Con 10 or Klor Con 8 potassium products and did not have or offer pricing data on other competitors. F. 419. Complaint Counsel's expert did not study the costs of Schering or other potassium supplement producers. F. 423. Complaint Counsel's expert did not study rebates, promotional allowances, or free goods, that affect the net pricing that Schering's customers received. F. 424.

Although Complaint Counsel sought to demonstrate that the price of K-Dur 20 rose, proof of one firm's prices rising, in a vacuum, cannot lead to any inference as to the relative price increase or decrease of Schering's K-Dur 20 product over time. An analysis under Indiana Federation requires that more be proven. See *Levine v. Central Florida Med. Affiliates*, 72 F.3d 1538, 1552 (11th Cir. 1996) (plaintiff's proof that defendant's prices (doctor's fees) had risen was legally insufficient because there was no proof of other doctors' fees or costs to compare those price increases with). Also, potassium purchasers had more than 20 firms to choose from to obtain therapeutically equivalent product, F. 31-37, clearly sufficient alternative choices to defeat an Indiana Federation claim. See *Flegel v. Christian Hosp., N.E.-N.W.*, 4 F.3d 682, 689 (8th Cir. 1993) (plaintiff provided insufficient evidence of detrimental effects under Indiana Federation where patients had the option of receiving care at other hospitals).

e. Complaint Counsel did not present a legally cognizable submarket under Brown Shoe

Brown Shoe v. United States, 370 U.S. 294, 325 (1962) introduced into merger law the concept of submarkets within the relevant market. *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986). The Supreme Court identified several "practical indicia" that may be used to delineate submarkets:

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The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

Brown Shoe, 370 U.S. at 325. "These indicia seem to be evidentiary proxies for direct proof of substitutability." Rothery Storage, 792 F.2d at 218; H.J., Inc., 867 F.2d at 1540 ("The same proof which establishes the existence of a relevant product market also shows (or in this case, fails to show) the existing of a product submarket.").

Complaint Counsel argues that a Brown Shoe analysis is not appropriate. Nevertheless, the Complaint specifically defined 20 milliequivalent extended-release potassium chloride tablets and capsules as a "narrower market" contained within the relevant market of all potassium chloride supplements approved by the FDA. Complaint at P21. Thus to determine whether "20 milliequivalent extended-release potassium chloride tablets and capsules" is a separate submarket, a Brown Shoe analysis follows.

1. "Industry Or Public Recognition" Of Distinct Markets

Complaint Counsel did not prove that the industry recognizes the existence of distinct markets between potassium chloride products and 20 mEq sustained-release potassium chloride tablets and capsules. Complaint Counsel's fact witnesses from Merck-Medco and United HealthCare, two important industry participants, provided no testimony to prove that the industry recognizes 20 mEq sustained-release potassium chloride products as a separate and distinct market from the overall potassium chloride market. F. 49-55.

In applying this factor, courts look to industry publications, the classification of a class of products in a separate class, perceptions of customers and the firms' marketing documents. See, e.g.,

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Moore Corp. v. Wallace Computer Servs., Inc., 907 F. Supp. 1545, 1576 (D. Del. 1995) (citation omitted). These materials uniformly support a broad potassium supplement market; Professor Bresnahan admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product with unique features. F. 81. Data from IMS has a single category, 60110, for "Potassium Supplement Chloride" in which K-Dur 20 is but one of more than 30 products sold by more than 25 different firms tracked by IMS. F. 83.

Professor Bresnahan conceded that Schering's marketing documents for K-Dur 20 use the entire potassium chloride supplement market as a measure of performance and also consider other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. F. 60. Schering tracked the progress of its substantial investment in advertising and marketing by monitoring market share gains in terms of the overall potassium market. F. 60. Even Bresnahan and Complaint Counsel relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. F. 60. The marketing documents of Schering's potassium rival, Upsher-Smith, demonstrate that one of the major competitors to the Upsher-Smith Klor Con product line, including the Klor Con 10 wax matrix, was K-Dur 20. F. 60 Upsher-Smith targeted K-Dur 20 in a series of advertisements urging doctors to substitute two Klor Con 10s for a 20. F. 64-69. Thus, the marketing perceptions of both companies were that K-Dur 20 competed in the broader potassium market. See, e.g., Moore, 907 F. Supp. at 1576 ("neither company has historically considered [the product at issue] as a category unto itself;" finding broader product market under Brown Shoe).

2. "Product's Peculiar Characteristics And Uses"

As detailed in the preceding section, Complaint Counsel did not prove that K-Dur 20 has "peculiar characteristics and uses" than other potassium supplements. All potassium supplements have the same purpose: to deliver potassium to hypokalemic patients. F. 43-48.

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3. "Unique Production Facilities"

Complaint Counsel presented no evidence that K-Dur 20 and its generic equivalents are manufactured in different plants or require different production facilities. In fact, Professor Bresnahan conceded at trial that the 10 and 20 mEq products are produced in the same plant. F. 85-86. With the same production facilities, the product facility factor cannot support a separate K-Dur 20 product market. See, e.g., *United States v. Consol. Foods Corp.*, 455 F. Supp. 108, 125 (E.D. Pa. 1978) (fresh and frozen institutional pies in same product market under Brown Shoe where "manufacturing facilities for both products are virtually the same").

4. "Distinct Customers"

Complaint Counsel did not prove that K-Dur 20 is directed toward a distinct class of customers. In fact, Brasnahan testified that there is no distinct class of customers that prefer K-Dur 20. F. 87-88 (Bresnahan unaware of any group of potassium deficient patients that cannot be treated by Klor Con 10; Bresnahan "has seen nothing in those terms."). Similarly, Phillip Dritsas testified that there is no unique subgroup of patients that can only take K-Dur 20. F. 87-88.

5. "Distinct Prices"

Under this factor, for product lines to be considered separate, each potentially definable market must have distinct prices. See *U.S. Healthcare, Inc. v. Healthsources, Inc.*, 986 F.2d 589, 598-99 (1st Cir. 1993). Complaint Counsel failed to introduce sufficient evidence or testimony of distinct prices in the 20 mEq sustained-release potassium chloride tablet and capsule market, as compared with other potassium products. Instead, Complaint Counsel's witness, Mr. Teagarden, conceded that K-Dur has the same relative price as other potassium chloride supplements. F. 89. Bresnahan conceded that branded potassium products had "comparable" prices to K-Dur 20. F. 89.

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The only specific pricing difference that appeared in Bresnahan's Report was a 30% pricing difference between only a small group of the potassium unbranded generic products, and this difference actually proved the cross-elasticity of demand between unbranded generics and K-Dur 20 in 1996. Bresnahan presented no statistical pricing study, and did not even have a pricing data set for K-Dur 20, a price data set for K-Dur 10 or for Klor Con 10, and for its competitors in the sale of potassium supplements. F. 91, 419, 428.

Bresnahan concedes that a pricing difference alone does not suffice to prove a separate product market. F. 91 Nor did he study the demand for various forms of potassium to calculate demand elasticities. F. 422. Professor Bresnahan did not study the ratio of Schering's prices to costs, so he is unable to evaluate any rise in Schering's price for K-Dur 20 as related or unrelated to costs. F. 423.

6. "Sensitivity To Price Changes"

Complaint Counsel did not introduce sufficient evidence to demonstrate that there is price sensitivity between other potassium chloride supplements and K-Dur 20. Complaint Counsel's sole expert economist failed to conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. F. 112, 113, 419-23. Bresnahan had no pricing data sets for Schering, Upsher-Smith, Apothecan, or any other potassium competitor. F. 419. Lack of this evidence undermines Complaint Counsel's claims. See, e.g., *Lantec, Inc. v. Novell, Inc.*, 146 F. Supp. 2d 1140, 1148-49 (D. Utah 2001) (granting defendants' motion for judgment as a matter of law against Section 1 and 2 claims "because there is no evidence on the costs of the various products or of how the consumer would react to a price increase in such costs, there is no evidence of price sensitivity" under *Brown Shoe* and thus plaintiffs' "evidence is insufficient to establish their definition of the relevant market").

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The record evidence actually shows not only price sensitivity in the market, but also K-Dur 20 losing some market share to other potassium chloride products. The record evidence showed that the 30% price difference between K-Dur 20 and the unbranded generic potassium products was causing the sales of the generic products to rise, as set forth in the K-DUR Marketing Plan (CX 20), written just six weeks after the June 1997 Agreement became effective:

Klor Con 10, a branded generic, has grown to 16% of total prescriptions. The category of generics has grown over a full point to 30% of total prescriptions. The growth in the generic market is due in part to the 30% price advantage over K-DUR 20, but managed care also plays a significant role.

F. 110; CX 20 (1998 K-Dur Marketing Plan, August 1, 1997, at SP 4040).

Similarly, the price sensitivity of the market to price reductions was dramatically demonstrated by the shift in sales to Apothecon, a new entrant in the sale of potassium supplements. F. 104-08. Price discounting was repeatedly noted in Upsher-Smith's potassium marketing documents. F. 104-08.

Furthermore, Bresnahan did not evaluate the brand advertising conducted by Schering. F. 424. Schering-Plough put millions of dollars into promoting the K-Dur brand and K-Dur 20 during the 1995-1997 time period. F. 411. Schering also invested heavily in free goods, rebates and other forms of discounting and marketing. 114-16. The magnitude of these expenditures demonstrates the price sensitivity of potassium supplement purchasers and the fact that Schering viewed itself as facing competition from various forms of potassium supplements prior to September 1, 2001. From October 1, 1997 to June 30, 2001, Schering spent \$136 million in rebates it paid K-Dur customers. F. 115.

Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and

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physician awareness activities. F. 411. This extensive advertising campaign was designed to compete against generic forms of potassium supplements. F. 411.

7. "Specialized Vendors"

The last Brown Shoe factor asks whether there are "specialized vendors" unique to K-Dur 20. No specialized vendors serve only 20 milliequivalent extended-release potassium chloride tablets and capsules. Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. F. 118. Prescriptions for extended-release potassium chloride supplements are dispensed at pharmacies. F. 118.

Complaint Counsel's witnesses did not establish by sufficient evidence any of these factors in order to prove that K-Dur 20 and its generic equivalents are a separate product market. Thus, an application of these "practical indicia" to the evidence presented at trial reveals that "K-Dur 20 and its generic equivalents" is not a separate product market.

E. First and Second Violations of the Complaint

The Complaint charges Respondents with four violations. The First and Second Violations of the Complaint charge that the agreements between Schering and its horizontal competitors, Upsher-Smith and AHP, unreasonably restrained commerce and therefore each agreement was an unfair method of competition.

1. The Legal Framework for Analysis of Horizontal Restraints

The FTC Act's prohibition of "unfair methods of competition" encompasses violations of other antitrust laws, including Section 1 of the Sherman Act, which prohibits agreements in restraint of trade. *California Dental Ass'n*, 526 U.S. at 763 n.3. The Commission relies on Sherman Act law in adjudicating cases alleging unfair competition. E.g., *Indiana Fed'n, Dentists*, 476 U.S. at 451-52 (Commission based its ruling that the challenged

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policy amounted to a conspiracy in restraint of trade that was unreasonable and hence unlawful under the standards for judging such restraint developed in the Supreme Court's precedents interpreting § 1 of the Sherman Act); *In re California Dental Assn.*, 121 F.T.C. 190, 292 n.5 (1996); *In re American Med. Assoc.*, 94 F.T.C. 701, 994 (1979).

Restraints on trade have been held unlawful under Section 1 of the Sherman Act, either when they fall within the class of restraints that have been held to be unreasonable per se, or when they are found to be unreasonable after a case-specific application of the rule of reason. In some circumstances, an abbreviated, or "quick look" rule of reason analysis may be appropriate. *California Dental*, 526 U.S. at 770. Complaint Counsel asserts that the challenged agreements are unreasonable restraints of trade under either the per se or rule of reason analysis. Although Complaint Counsel does not specifically urge "quick look" treatment, because many of the arguments Complaint Counsel advances relate to an abbreviated rule of reason approach, this method of analyzing the agreements is also addressed. Regardless of the method of analysis employed, the essential inquiry remains the same--whether or not the challenged restraint enhances or impairs competition. *National Collegiate Athletic Assn. v. Bd. of Regents*, 468 U.S. 85, 104 (1984) ("NCAA").

2. The Per Se Approach Is Not Applicable

"Most antitrust claims are analyzed under a 'rule of reason'" *State Oil Co. v. Kuhn*, 522 U.S. 3, 10 (1997) (citations omitted); *Standard Oil*, 221 U.S. 1, 62 (1911); *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) (courts generally determine the reasonableness of a particular agreement by reference to the surrounding facts and circumstances under the rule of reason). Courts are free to depart from this analysis, and adopt per se rules, only in limited circumstances, after they have had sufficient experience with a particular type of restraint to know that it is manifestly anticompetitive. *Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 9 (1979); *Continental T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977) (the per se

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rule should only apply to conduct that has a "pernicious effect on competition" and "lack[s] . . . any redeeming virtue"). Examples of such practices are horizontal price fixing, *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940), *FTC v. Sup. Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990); agreements to reduce output, *NCAA*, 468 U.S. at 99; territorial divisions among competitors, *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972); and certain group boycotts. *Northwest Wholesale Stationers v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985). "Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984). See also *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972).

To fit its allegations into the per se category, Complaint Counsel advances two theories. First, Complaint Counsel characterizes the agreements as "temporal market allocations," dividing the time remaining on Schering's patent. Second, Complaint Counsel asserts that the agreements reduced output and increased prices by keeping Upsher-Smith's and AHP's cheaper generic versions of K-Dur 20 off the market until September 2001 and January 2004, respectively. However, the settlement agreements fit neither of these molds. Further, because an agreement to settle patent litigation must be examined in the context in which the agreement arose, the per se approach is not appropriate.

a. Complaint Counsel has not presented a per se market division case

Complaint Counsel asserts, "each agreement is in economic substance a temporal market allocation arrangement, in which sales of K-Dur 20 are reserved to Schering for several years, while Upsher-Smith and AHP are required to refrain from selling their generic versions of K-Dur 20 during that time period. As such, each constitutes a horizontal market allocation agreement, a

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classic per se violation." CCPTB at 65. However, this case does not present a straightforward market division case. Rather, the claims, as framed by Complaint Counsel, raise two novel issues. First, whether a patent holder and a challenger to that patent can settle patent litigation with an agreement that divides the time remaining on the patent. Second, whether a patent holder can make a "reverse payment" to settle a patent dispute.

The classic per se violation cases involve territorial or geographic divisions of markets. *Palmer*, 498 U.S. at 49-50 (competitors agreed not to enter each other's territories and to share profits from sales in one of those territories); *Topco Assoc.*, 405 U.S. at 607-08 ("One of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"). With the exception of the *Cardizem* and *Terazosin* cases, Complaint Counsel has cited no case that holds that a "temporal market allocation" is a per se violation and no case that prohibits a patent holder from allocating the time remaining under its patent by retaining the exclusive rights guaranteed by the patent for a number of years and then granting licences under the patent to allow manufacturers of generic versions to compete for the remaining time. See *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000). See also *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 811 (D.C. Cir. 2001).

The *Cardizem* and *Terazosin* cases can be distinguished on numerous grounds. The critical difference, though, is that those agreements did not involve final settlements of patent litigation; and they did not involve agreements permitting the generic company to market its product before patent expiration. In *Terazosin*, the court found: "Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage." 164 F. Supp. 2d at 1350. Likewise, in *Cardizem*, the challenged agreement "did not resolve the pending patent claims; . . . Rather than facilitating or fostering an expeditious resolution

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of the HMRI/Andrx patent infringement suit, . . . [the agreement and payments] created the incentive to pursue the litigation beyond the district court and through the appellate courts." 105 F. Supp. 2d at 705.

In addition, Complaint Counsel's challenge to what Complaint Counsel has characterized as "reverse payments" is far from an "established" antitrust violation. The novelty of challenges to "reverse payment" patent infringement settlements was acknowledged by Complaint Counsel's expert witnesses at trial. Professor Bresnahan testified that there was no economic literature on the topic of reverse payments prior to the filing of suit in this case. Bresnahan, Tr. 644-45. Professor Bazerman testified that he had never heard of the phrase "reverse payments" prior to his work in this case. Bazerman, Tr. 8569. Applying a per se rule to a practice that is so new would be inappropriate. *Broadcast Music, Inc.*, 441 U.S. at 9; *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 344 (1982).

Courts have been reluctant to create new per se rules. *Indiana Fed'n of Dentists*, 476 U.S. 447, 458-59 (1986) ("We have been slow . . . to extend per se analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious."); *Broadcast Music, Inc.*, 441 U.S. at 9 ("It is only after considerable experience with certain business relationships that courts classify them as per se violations.") See also *Maricopa County*, 457 U.S. 332, 344 (1982) ("Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.").

The few decisions by U.S. district courts adjudicating claims arising from the agreements entered into between Hoechst Marion Roussell and Andrx and between Abbott and Zenith and Geneva hardly constitute "considerable" experience. Further, the factual differences between the challenged agreements in *Cardizem* and *Terazosin* and the challenged agreements here distinguish those cases from the instant one. Without established case law holding

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that temporal market allocations pursuant to a patent or payments in connection with the settlement of patent litigation are per se violations, the "considerable experience" needed to support per se condemnation is lacking and application of the per se rule is inappropriate.

b. Complaint Counsel has not presented a per se case of reduced output and increased prices

Complaint Counsel alleges "that the challenged payments to stay off the market directly limit competition on price and output and are inherently likely to delay the entry of lower-priced alternatives and to enable Schering to maintain high prices without fear of losing market share." CCPTB at 65. This case, however, does not present a straightforward case of an agreement to reduce output or set prices.

The agreements, on their face, set no limits on output or prices and Complaint Counsel does not argue that Schering dictated the price at which Upsher-Smith and ESI may sell their products or the quantities they may sell upon entry. The agreements do, however, establish that Upsher-Smith and ESI may not enter the market with their generic versions of K-Dur 20 until September 2001 and January 2004, respectively. Complaint Counsel makes the argument that, by setting these entry dates, Respondents, in effect, limited the output--by eliminating Upsher-Smith's and ESI's output--that would have been available for the periods of up until September 2001 and January 2004. Complaint Counsel further argues that, because Schering was unrestrained from competition from the generics, the agreements enabled Schering to increase prices by charging supra competitive prices for K-Dur 20.

Complaint Counsel's argument ignores the critical fact that these agreements are agreements to settle patent litigation. There is no evidence that the '743 patent is invalid. F. 124. There is no evidence that Schering's initiation of the patent infringement suits against Upsher-Smith and ESI was not for purposes of defending the '743 patent. F. 128, 331. Indeed, Hatch-Waxman encourages

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patent holders to initiate patent litigation to defend their patents by requiring ANDA applicants to notify patent holders of Paragraph IV Certifications and imposing a 45 day framework for patent holders to initiate patent infringement suits against generic manufacturers. 21 U.S.C. § 355(j); Mylan, 139 F. Supp. 2d at 9. Unless determined to be invalid, the '743 patent gives Schering the right to limit output - by excluding manufacturers of infringing drugs from the market until September 2006. See 35 U.S.C. § § 101, 271, 281. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969) ("The heart of his legal monopoly is the right to . . . prevent others from utilizing his discovery without his consent."). And, this patent gives Schering the right to charge monopolistic prices for its patented product. "Such an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *United States v. Studiengesellschaft Kohle, M.B.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981).

It is not immediately obvious whether output was reduced and prices were increased by operation of Schering's legal, patented monopoly or by operation of the agreements entered into between Schering and Upsher-Smith and Schering and ESI. Further, because it is not immediately obvious that Upsher-Smith or ESI could have entered the market sooner than the agreed upon dates, it is not immediately obvious that output was reduced. "The Supreme Court has made it clear that the per se rule is a 'demanding' standard that should be applied only in clear cut cases." *Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) (citing *Continental T.V.*, 433 U.S. at 50). Because this case does not present a clear cut case of restraints where the economic impact is "immediately obvious" (*Indiana Fed'n of Dentists*, 476 U.S. at 459), per se treatment is not appropriate and a full rule of reason analysis is required.

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c. The agreements challenged by Complaint Counsel are not in the class of agreements with no redeeming virtues

Settlements of intellectual property lawsuits are not in a class of per se agreements that, in the words of the Supreme Court in *White Motor Co. v. United States*, 372 U.S. 253 (1963) "lack . . . any redeeming virtue." *Id.* at 263. All settlements have redeeming virtue, providing important procompetitive benefits that must be taken into consideration in any antitrust analysis. See, e.g., *Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979) (court must balance "deeply-instilled policy of settlement[s]" against claim that patent settlement unreasonably restrained trade); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes who support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute."). For example, one of Schering's expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. F. 384. Mr. Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. F. 384. This is especially true of settlements of patent infringement cases, like the *Upsher-Smith* and *HSI* settlements. See *Grunin v. Int'l House of Pancakes*, 53 F.2d 114, 123 (8th Cir.), cert. denied, 423 U.S. 864 (1975) ("The very purpose of compromise is to avoid the delay and expense of such a trial."); *Boston Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 270-71 (D. Mass. 1997) (upheld settlement agreement as not anticompetitive based on the "general rule that settlements and cross-licensing agreements do not, without something more, violate the antitrust laws."). Under the *Upsher-Smith* settlement agreement, for example, consumers are enjoying low priced generic versions of K-Dur 20 today. In the absence of the settlement, it is impossible for anyone to say whether there

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would be generic competition today or not because we can't know who would have won the litigation. See Bresnahan, Tr. 8230.

Although the Supreme Court has utilized the per se approach in cases involving settlements of patent disputes, in each of those cases, the patent holder engaged in conduct that reached beyond the rights conferred by the patent and engaged in conduct that was in violation of antitrust law. E.g., *United States v. Masonite Corp.*, 316 U.S. 265, 282-83 (1942) (finding licensing agreement where patent holder set prices a violation of Sherman Act); *United States v. Singer Mfr. Co.*, 374 U.S. 174, 197 (1963) (finding patent interference settlement unlawful where the dominant purpose of a settlement was not to settle priority, but to exclude a mutual competitor of the parties); *U.S. v. New Wrinkle Inc.*, 342 U.S. 371, 380 (1952) (finding a licensing agreement between patent owner and manufacturer which served as means for owner to set prices a per se violation of Sherman Act); *U.S. v. Line Material Co.*, 333 U.S. 287, 314-15 (1948) (finding agreements to cross license patents which fixed the price of the patented device a per se violation). As analyzed below, the conduct engaged in by Schering was not proven to be beyond the rights conferred by the patent. Accordingly, these cases do not command the application of the per se rule.

d. The effects of the agreements cannot be presumed

Complaint Counsel argues that the anticompetitive effects of these agreements are so clear that the restraints should be deemed per se unreasonable. CCPTB at 46, 65. *Northern Pacific Ry. v. United States*, 356 U.S. 1, 5 (1958) ("There are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable."). It is inappropriate in this case, however, to presume effects, for to do so would require a presumption that the '743 patent was either invalid or not infringed by Upsher-Smith's and ESI's products. As discussed in Section E.4.b. *infra.*, to make this presumption would be contrary

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to law and the substantial, reliable evidence presented at trial. Accordingly, effects will not be presumed and the agreements will be analyzed under the rule of reason approach.

3. The Quick Look Approach Is Not Applicable

An abbreviated or "quick look" analysis under the rule of reason may be utilized when "the great likelihood of anticompetitive effects can easily be ascertained." *California Dental Ass'n*, 526 U.S. at 770. Quick look analysis may be appropriate to analyze agreements to restrict output. *NCAA*, 468 U.S. at 110 ("naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis"). However, where the "anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints" than can be performed using an abbreviated rule of reason analysis. *California Dental Ass'n*, 526 U.S. at 759.

The case presented by Complaint Counsel fails to present a situation in which the likelihood of anticompetitive effects is obvious. It is possible that Upsher-Smith and ESI might have entered the market prior to September 2001 and January 2004, respectively. However, it is also of course possible that they might not have entered the market until September 2006, upon the expiration of Schering's patent, or not at all. Faced with a set of different conflicting possibilities, the Supreme Court in *California Dental Ass'n*, held "that the plausibility of competing claims about the effects of the professional advertising restrictions rules out the indulgently abbreviated review to which the Commission's order was treated. The obvious anticompetitive effect that triggers abbreviated analysis has not been shown." 526 U.S. at 778.

Here, Complaint Counsel has presented one plausible explanation for Schering's payments of \$ 60 million to Upsher-Smith and of \$ 15 million to ESI--that these were payments to delay the generics' entry in the market. But, as analyzed *infra*, this explanation is based largely on the opinion testimony of Complaint Counsel's economic expert that manufacturers of brand

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name drugs have economic incentives to keep generic manufacturers off the market in order to retain monopoly profits. This explanation is also based on the opinion testimony of Complaint Counsel's valuation expert who testified that Schering's payment to Upsher-Smith was grossly excessive. Respondents also offer plausible explanations, supported by evidence, - that the payments were made to settle legitimate patent disputes and for separate pharmaceutical products at fair value. Given the plausibility of competing claims about whether the payments were only for delay, the obvious anticompetitive effect "that triggers abbreviated analysis has not been shown" (California Dental Ass'n, 526 U.S. at 778) in this case.

4. Under the Rule of Reason, Complaint Counsel Has Not Demonstrated That These Agreements Are Illegal

a. Complaint Counsel must prove effect on competition

In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition. "The Supreme Court has made clear that the rule of reason contemplates a flexible enquiry, examining a challenged restraint in the detail necessary to understand its competitive effect." In re California Dental Assoc., 121 F.T.C. at 308 (citing NCAA, 468 U.S. at 103-110) "An analysis of the reasonableness of particular restraints includes consideration of the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption." Topco Assoc., 405 U.S. at 607. See also *Todd v. Exxon Corp.*, 275 F.3d 191, 214 (2d Cir. 2001) (plaintiff must present evidence to support allegation that challenged conduct had anticompetitive effect); *All Care Nursing Service, Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 749 (11th Cir. 1998) ("To satisfy the rule of reason, the plaintiff must prove that the [conduct] had an adverse effect on competition.").

The fact that a case proceeds under Section 5 of the FTC Act does not alter the requirement that anti-competitive effects must be proved with evidence. See *California Dental Assoc. v. FTC*,

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224 F.3d 942, 958-59 (9th Cir. 2000) (FTC's failure to demonstrate substantial evidence of a net anticompetitive effect resulted in remand with direction that the FTC dismiss its case). See also *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 582 (9th Cir. 1980) (absence of evidence reflecting an anticompetitive effect rendered Commission order unenforceable); see also *E.I. duPont de Nemours & Co. v. FTC*, 729 F.2d 128, 141 (2d Cir. 1984) (challenged practice can only be found to be unfair method of competition under § 5 if weight of evidence shows competition substantially lessened and clear nexus between challenged conduct and adverse effects); see also *Interpreters*, 123 F.T.C. at 640 (Complaint Counsel failed to demonstrate anticompetitive effects of certain association rules).

The cases relied upon by Complaint Counsel, *Summit Health, Ltd. v. Pinhas*, 500 U.S. 322, 330 (1991) and *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 785 (1975), do not support Complaint Counsel's proposition that Complaint Counsel need not prove or quantify actual effects to support a claim under Section 5. *Summit Health* holds that a defendant need not prove an actual effect on interstate commerce in order to establish federal jurisdiction. 500 U.S. at 330 ("If establishing jurisdiction required a showing that the unlawful conduct itself had an effect on interstate commerce, jurisdiction would be defeated by a demonstration that the alleged restraint failed to have its intended anticompetitive effect. This is not the rule of our cases.") (citation omitted). *Goldfarb* holds that in order to establish that a challenged activity affects interstate commerce, plaintiff need not quantify the expected effect. 421 U.S. at 785. "Once an effect is shown, no specific magnitude need be proved." *Id.* Thus, Complaint Counsel is not relieved of showing effects simply because this case was brought under Section 5 of the FTC Act, and not under Section 1 of the Sherman Act.

b. Complaint Counsel has not proven that the agreements delayed competition

Complaint Counsel alleges that the agreements between Schering and Upsher-Smith and between Schering and ESI

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harmed competition because the agreements had the effect of delaying the introduction of Upsher-Smith's Klor Con M20 and ESI's Micro-K20 to the market. It is undisputed that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. It is undisputed that under the June 17, 1997 Agreement, Upsher-Smith gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than five years earlier than the expiration of the '743 patent. F. 156. It is undisputed that under the handwritten settlement agreement and final settlement agreement between Schering and ESI, ESI gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than two and a half years earlier than the expiration of the '743 patent. F. 367, 372. And, it is undisputed that under license Upsher-Smith began selling Klor Con M20 on September 1, 2001. F. 94.

What is disputed is whether Upsher-Smith and ESI could have entered the market any earlier than September 1, 2001 and January 1, 2004, respectively. If Upsher-Smith and ESI could have legally entered the market prior to September 2001 and January 2004, but were paid only for delay and not as part of a legitimate settlement, as Complaint Counsel alleges, then the challenged agreements would have anticompetitive effects. Thus, to prove anticompetitive effects, Complaint Counsel must prove that better settlement agreements or litigation results would have resulted in Upsher-Smith and ESI selling their generic equivalents prior to September 1, 2001 and January 1, 2004. Complaint Counsel did not demonstrate this. Nor has Complaint Counsel brought forth evidence that the entry dates agreed upon were "unreasonable." Thus, without sufficient evidence to prove that Upsher-Smith or ESI would have entered the market sooner than the agreements allow, Complaint Counsel failed to prove that any unlawful delay resulted from the agreements.

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(i) The '743 patent operates to exclude all non-infringing products until September 5, 2006

"A patent shall be presumed valid," 35 U.S.C. § 282. This is long established law that cannot be ignored. E.g., *Doddridge v. Thompson*, 22 U.S. 469, 483 (1824) (a patent is presumed to be valid, until the contrary is shown); *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 995 (Fed. Cir. 1995) (patents are presumed to be valid; until invalidity is proven, the patentee should ordinarily be permitted to enjoy the fruits of his invention). But see *Cardizem*, 105 F. Supp. 2d at 700 (characterizing defendants' arguments as based on "erroneous presumptions" by Andrx regarding whether a generic drug would infringe the patent). However, *Cardizem* cites no authority to support this apparent presumption of the pending patent case and to the extent it is a presumption of invalidity or non-infringement, it is contrary to well settled precedent. A presumption of infringement or invalidity of a patent is tantamount to grafting a section onto the Hatch-Waxman Act which is clearly not there. The making of the laws is a function of our Congress.

Under its '743 patent, Schering had the legal right to exclude Upsher-Smith from the market until Upsher-Smith either proved that the '743 patent was invalid or that its product, Klor Con M20, did not infringe Schering's patent. Similarly, Schering had the legal right under its '743 patent to exclude ESI from the market until ESI either proved that the '743 patent was invalid, or that its product, Micro-K20, did not infringe Schering's patent. *Doddridge*, 22 U.S. at 483; *Cordis*, 780 F.2d at 995. Application of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder. In *Independent Service Organizations Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (court must give "due consideration to the exclusivity that inheres in the patent grant"); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("Some measure must guaranteed that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws."); *Bement v. National Harrow Co.*, 186 U.S. 70, 88 (1902).

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While Complaint Counsel acknowledges that the '743 patent gives Schering the right to exclude all infringing products, Complaint Counsel argues that antitrust laws prohibit Schering from paying Upsher-Smith and ESI to stay off the market. However, Complaint Counsel has not established that Schering paid Upsher-Smith and ESI to stay off the market because Complaint Counsel has not proved that Upsher-Smith or ESI could have even been on the market prior to the expiration of the '743 patent.

Indeed, Complaint Counsel acknowledges that it cannot prove that Upsher-Smith and ESI could have been on the market prior to September 5, 2006. In its post trial brief, Complaint Counsel states that it is impossible to reliably determine whether the Upsher-Smith and ESI products did not infringe Schering's patent or whether the alleged infringers would have prevailed in the infringement suits. CCPTB at 67-76. The evidence presented at trial confirms that the likely outcome of the patent disputes cannot reliably be predicted. *Id.*; F. 394. And because the outcome of the patent disputes cannot be predicted, the date on which Upsher-Smith and ESI could have entered, but for the agreements, cannot be determined. Complaint Counsel argues:

Respondents, in advocating a test for competitive harm that cannot be done reliably, urge a rule that would effectively immunize settlements involving payments not to compete. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach patent settlements that involve payments for delayed entry, the threat of serious harm to consumers is too great, and the likelihood of deterring procompetitive agreements is too small, to justify the approach advocated by respondents.

CCPTB at 67-76

Complaint Counsel's argument may hold intellectual appeal. However, simply because, based upon the theories it advanced in

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this case, Complaint Counsel cannot prove whether Upsher-Smith and ESI would have come on the market earlier than September 2001 and January 2004, but for the \$ 60 million and \$ 15 million payments, does not relieve Complaint Counsel of its burden of proof. In *Andrx Pharm.*, 256 F.3d 799, the court, on a motion to dismiss, held, "one can fairly infer . . . that but for the Agreement, Andrx would have entered the market." *Id.* at 809. The court noted that Hoechst's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. *Id.* at 813. But in this case, after a lengthy trial, there is substantial evidence to support Respondents' defense that the agreements were legitimate agreements to settle vigorously contested patent litigation, and, in the case of Upsher-Smith, that the payment from Schering to Upsher-Smith was for Niacor-SR and the other drugs licensed from Upsher-Smith to Schering; and, in the case of ESI, that the patent litigation would not have settled without a payment from Schering to ESI and the licensing of other drugs from ESI to Schering. In the face of this substantial evidence, to agree with Complaint Counsel would require an inference or presumption of what Complaint Counsel has not proved and would effectively shift the burden of proof to Respondents, contrary to law, as discussed *supra*.

Complaint Counsel, relying on *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001), argues that it is not required to prove what would have happened, "but for" the challenged conduct. In *Microsoft*, the court noted, "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." *Id.* The challenge for Complaint Counsel here is much narrower. Complaint Counsel is not asked to reconstruct a hypothetical technological development, but to demonstrate that, absent Schering's payments to Upsher-Smith and ESI, Upsher-Smith and ESI would have come on the market earlier than the agreements allowed. Complaint Counsel has not done so.

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Further, even though the government in *Microsoft* was not required to reconstruct a product's hypothetical development in a world absent the defendant's exclusionary conduct, the government was required to prove effects:

First, to be condemned as exclusionary, a monopolist's act must have an 'anticompetitive effect.' . . . Second, the plaintiff, on whom the burden of proof of course rests, . . . must demonstrate that the monopolist's conduct indeed has the requisite anticompetitive effect.

Microsoft, 253 F.3d at 58-59 (emphasis added). Thus, *Microsoft* does not relieve Complaint Counsel of proving the payments delayed entry.

(ii) Upsher-Smith and ESI would not have come on the market until the resolution of the patent infringement suits

The Hatch-Waxman Act does not provide immunity for patent infringement damages and there is no substantial evidence to demonstrate that Upsher-Smith and ESI would have entered the market before resolution of the patent infringement suits. The court, in *Cardizem*, accepted the plaintiffs' allegations as true, as it must on a motion to dismiss, that Andrx's generic drug would have entered the U.S. market on or about July 9, 1998, the date on which Andrx received FDA approval, but for its agreement with Hoechst. *Cardizem*, 105 F. Supp. 2d at 649. However, FDA approval does not mean generic entry will occur while patent disputes are unresolved. Since FDA approval of an ANDA does not shield a generic manufacturer from liability. 35 U.S.C. § 284; *King Instruments Corp. v. Perego*, 65 F.3d 941, 948 (Fed. Cir. 1995). The prudent practice, then, is for generic manufacturers to await the conclusion of patent litigation before marketing a product and risking financial ruin.

In this case, Upsher-Smith and ESI each received final FDA approval to market their generic versions of Schering's K-Dur 20 by November 1998 and June 1999, respectively. At the

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conclusion of trial, there is no credible evidence of when, if ever, ESI would have otherwise entered the market and, there is credible evidence that Upsher-Smith would not have entered the market if it was still entangled in patent litigation, even at the end of the 30-month stay and upon FDA approval. F. 391-92. For Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "foolhardy" and potentially could have had dire consequences. F. 391-92.

c. Complaint Counsel did not prove that the payments were not to settle the infringement cases and for drugs licensed to Schering

(i) Upsher-Smith

The claims against Schering and Upsher-Smith rest upon the allegation that the \$ 60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products. The Complaint alleges: "The \$ 60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering." Complaint P45. The Complaint alleges that the royalty payments were in fact payments to delay the introduction of Upsher-Smith's AB-rated generic to K-Dur 20. Complaint P64. Complaint Counsel have described the \$ 60 million in royalty payments as a "veil," "disguise," "sham," and "cover." CCPTB at 2-3, 6, 8, 26, 34.

Prior to trial, Complaint Counsel acknowledged that its case would fail if it could not prove that Schering paid Upsher-Smith for delay. At a July 25, 2001 hearing, Complaint Counsel answered a question from the bench as follows:

JUDGE: I guess I need to ask you one more question. Then are you saying the Government has to prove the payment was for delay in order to win this case?

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MR. KADES: Absolutely. That's what we will prove at trial. . . .

7/25/01 Tr. at 34. In its Post Trial Brief, Complaint Counsel reaffirmed that the Complaint requires them to prove that the \$ 60 million was for delay rather than for a bona fide product license: "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with 'side deals' to such an agreement." CCPTB at 43. Complaint Counsel's expert witness economist, Professor Bresnahan, agreed that a side deal at fair value did not raise competitive concerns:

Q: All right, sir. Now, similarly had Upsher-Smith and Schering-Plough entered into an agreement that contained a side deal at fair value, same negotiation, they negotiate entry date and then they have a side licensing deal, and it contains fair market value consideration being exchanged between the parties, that would not flunk the Bresnahan test. That would not be anticompetitive according to you. Is that correct?

A: That's right.

Q: All right. So you don't have a problem with side agreements, as such; you want to make sure there's no net positive value flowing to the generic firm. Is that correct?

A: That's--that's my test, yes.

F. 172. Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." F. 172.

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At trial, the evidence established that the June 17, 1997 Agreement between Schering and Upsher-Smith was a type of transaction that Complaint Counsel and their economist concede to be permissible: it was a settlement of a patent dispute by an agreement on a date of entry, with a side deal supported by fair value as determined at that time. The fact testimony at trial was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction, and that Schering's royalty payments to Upsher-Smith were payments for the products being licensed to Schering, together with certain production rights. Contemporaneous documentary evidence, such as Mr. Audibert's commercial assessment and Schering's Board Presentation, corroborated that testimony. The opinion testimony of Complaint Counsel's expert witnesses, based largely upon theory, did not impeach that unrebutted and credible fact evidence. The substantial, reliable evidence refutes Complaint Counsel's allegation that the \$ 60 million paid to Upsher-Smith was "unrelated" to the products being licensed.

(A) The Evidence Establishes That The Niacor-SR License Was a Bona Fide Side Deal For Fair Value

Abundant evidence at trial established that the \$ 60 million paid by Schering was fair value for Niacor-SR and the other licensed products. Upsher-Smith had for years invested heavily in Niacor-SR and in mid-1997 it appeared to be a highly promising product. F. 191-92. Start-up company Kos Pharmaceuticals had achieved a market capitalization of approximately \$ 400 million almost entirely on the promise of its extended-release niacin product Niaspan, which, like Niacor-SR, had not yet obtained FDA approval for marketing. F. 152. Schering had a documented, pre-existing interest in an extended-release niacin product to enter the cholesterol-fighting market. F. 201-19. In the months preceding the licensing agreement with Upsher-Smith, Schering had engaged in extended negotiations with Kos over a possible U.S. copromotion venture. F. 201-08. Schering had made a substantial written proposal to Kos, but Kos rejected it. F. 214-19. Shortly thereafter, the Niacor-SR opportunity arose. F. 138.

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When the Upsher-Smith opportunity arose, Schering's James Audibert undertook a commercial assessment of Niacor-SR. F. 228. Mr. Audibert had extensive experience in the marketing of extended-release formulations, had considerable experience with cholesterol-reducing drugs, and had been involved in Schering's discussions with Kos relating to Niaspan. When he prepared his valuation of Niacor-SR, Mr. Audibert was not aware that the licensing opportunity had arisen in the context of a side deal to a patent settlement and was not aware of the amount of money that was being asked for the license rights by Upsher-Smith. F. 251. Mr. Audibert stated in his commercial assessment: "Niacor SR is expected to be launched in early 1999 with 3rd-year sales of \$ 114 million." F. 251. "In summary, Niacor SR offers a \$ 100 [ILLEGIBLE WORD] million sales opportunity for Schering-Plough." F. 254.

The other pharmaceutical products that Upsher-Smith licensed to Schering, prevalite, Klor-Con 8, 10 and M20, and pentoxifylline, also had value. According to the presentation given to Schering's Board of Directors, Schering's staff forecasted sales "to be \$ 8 million a year in the first full year of launch, growing to \$ 12 million a year in the second full year, and then gradually declining in year four and thereafter." F. 165.

The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. F. 163. The presentation given to Schering's Board of Directors stated that, in the course of Schering's discussions with Upsher-Smith, Upsher-Smith indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream to make up for the income that they had projected to earn from sales of Klor-Con, had they been successful in their suit. F. 163. The Board was informed that Schering had made it clear to Upsher-Smith that any such deal would have to stand on its own merit, independent of the settlement. The Board presentation provided sales projections for Niacor-SR of \$ 100 million plus in annual sales and showed a net present value of \$ 225-265 million for the Niacor license. F. 164.

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(B) Complaint Counsel did not meet its burden of proving that the Niacor-SR License was not a bona fide side deal for fair value

(i) Dr. Levy

To prove that the \$ 60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products, Complaint Counsel proffered Dr. Nelson L. Levy, an expert "in the field of pharmaceutical licensing and pharmaceutical valuation." F. 174. Dr. Levy testified that the \$ 60 million payment made by Schering to Upsher-Smith cannot be considered to have been a license fee for Niacor SR and the five generic products licensed. F. 315. Dr. Levy had three bases for this opinion. First, Levy concluded that the \$ 60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, and greatly surpassed the non-contingent fees paid by Schering in other unrelated pharmaceutical transactions. F. 290, 296. Second, Levy bases his conclusion on his opinion that the due diligence conducted by Schering for Niacor-SR was strikingly superficial relative to industry standards on due diligence and Schering's own due diligence practices. F. 301-03. Third, Levy bases his conclusion on his opinion that after the settlement agreement was executed, neither Schering nor Upsher-Smith undertook behavior consistent with parties who had just entered into a licensing transaction, for which Schering committed to pay \$ 60 million. F. 315-18.

Dr. Levy's testimony is contradicted by the greater weight of the evidence. Schering presented substantial, reliable evidence demonstrating that Niacor-SR and the other licensed products were valued at \$ 60 million. F. 258-61. Schering presented substantial, reliable evidence demonstrating that Schering performed due diligence on Niacor-SR. F. 243-61. And, Respondents presented substantial, reliable evidence to explain Respondents' post deal conduct and attendant decisions not to pursue Niacor-SR. F. 262-74.

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Furthermore, Dr. Levy's testimony is accorded less weight for three reasons. First, he performed no quantitative analysis of Niacor-SR or any of the other 5 products Schering received under the license agreement and did not consider the market value of Kos. F. 293. Second, Dr. Levy's opinions regarding value of Niacor-SR are founded in part on his conclusions regarding the safety and efficacy of Niacor-SR and his testimony demonstrated he lacked expertise in the area of cholesterol-lowering drugs and niacin. F. 308-14. Third, Dr. Levy's conclusion that the parties' post deal conduct is not behavior consistent with parties who had just entered into a licensing transaction for which Schering committed to pay \$ 60 million is rebutted by the evidence Respondents presented on their post deal conduct and discredited because Levy did not review many of the documents reflecting the parties' communications and continued work on the licensed products. F. 315-18.

(ii) Professor Bresnahan

Complaint Counsel also offered the expert testimony of Professor Bresnahan to prove Schering's payment was not for the Niacor license. Bresnahan did not attempt to value the rights Schering obtained under the licensing agreement and did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of \$ 225-265 million presented to Schering's Board of Directors. F. 319. Instead, Bresnahan applied a "revealed preference" test and a "market test" and analyzed the parties' incentives to opine that the \$ 60 million payment was not for the Niacor license. F. 320-26.

Under Bresnahan's "revealed preference" test, Bresnahan concluded that Schering's turning down of Kos' Niaspan "revealed" that Schering was not willing to make a large upfront payment for the comparable Niacor-SR product. F. 320. However, Schering demonstrated a genuine interest in Kos' sustained-release niacin product, projected substantial sales for that product, engaged in an extended dialogue with Kos, and made a serious offer incorporating a major financial commitment commensurate with the profit split under the contemplated co-promotion

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arrangement. F. 201-19. The substantial, reliable evidence demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. F. 217-19.

Professor Bresnahan testified that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, Niacor-SR was not highly valued enough in the marketplace to justify a non-contingent payment, and therefore the \$ 60 million non-contingent payment made by Schering to Upsher-Smith was not for Niacor-SR. However, in June 1997, Upsher-Smith was still in active discussions with a variety of companies to market Niacor-SR. F. 325, 196. Upsher-Smith executives believed that potential European licensees were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. Because Upsher-Smith terminated its marketing efforts after signing the exclusive agreement with Schering on June 17, 1997, no conclusions as to Niacor-SR's value can be drawn from this ongoing process. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR licence. F. 326. This evidence refutes the conclusion Bresnahan reached using his market test.

Professor Bresnahan also testified that Schering and Upsher-Smith had incentives to engage in a transaction trading a payment for delay and acted on those incentives. Ultimately, Professor Bresnahan was compelled to acknowledge that theoretical "incentives" hardly constitute evidence of actual improper conduct:

Q: Professor, is it your view that if a person has an economic incentive to violate the law, that leads to the conclusion that they did so?

A: No.

Bresnahan, Tr. 1105. These "incentives" are not legally dispositive. See, e.g., *Serfeez v. Jewel Food Stores*, 67 F.3d 591,

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600 (7th Cir. 1995) (holding that "the presence of an economic motive is of very little probative value" and that "the mere existence of mutual economic advantage, by itself, . . . supplies no basis for inferring a conspiracy"). Contrary to the theory offered by Bresnahan, the record testimony from all of the participants in the negotiations provides direct evidence that the parties did not exchange money for delay. F. 322-26.

The presentation made to Schering's Board of Directors when it approved the licensing agreement reported that Upsher-Smith had expressed a desire for "an income stream to replace the income that [it] had anticipated earning if it were able successfully to defend against Key's infringement claims." F. 163. As Professor Bresnahan acknowledged, (Bresnahan, Tr. 572-573), the presentation also reported: "we informed them that any such deal should stand on its own merit independent of the settlement." F. 163. The remainder of the presentation contained a detailed discussion and financial analysis justifying the licensing opportunity on its own merit. F. 163-66. Despite Professor Bresnahan's opinion otherwise, the Schering Board presentation confirms Schering's insistence that any licensing royalty payment to Upsher-Smith had to be independently supported by fair value.

(C) The terms of the June 17, 1997 agreement

Professor Bresnahan opined that Paragraph 11 of the June 17, 1997 agreement "links" Schering's royalty payments to the September 1, 2001 entry date. Bresnahan, Tr. 535-536. Paragraph 11 expressly describes the three payments totaling \$ 60 million as "up-front royalty payment[s]." As evidenced by the negotiations leading up to June 17, 1997 agreement, Upsher-Smith and Schering each intended the term "royalty" to reflect that Schering would be paying for the licenses and associated production rights it was receiving from Upsher-Smith. This understanding of "royalty" comports with the common understanding of the term. See, e.g., *Sierra Club, Inc. v. C.J.R.*, 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that "royalty" commonly refers to a payment made to the owner of property for permitting another to use the property") (citing Black's Law Dictionary 1330-31 (6th ed.

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1979)); see also Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization* § 28 (3d ed. 2000) ("The patent holder may produce the product (or use its new process) or license (permit) others to produce it in exchange for a payment called a royalty.") (emphasis in original). Furthermore, in Paragraph 11, the designated payor of the "royalty" payments is "SP Licensee." "SP Licensee," which is first defined in Paragraph 7, is the recipient of Upsher-Smith's licenses in Paragraphs 7 through 10. F. 156, 161. The only natural and normal reading of Paragraph 11 is that "SP Licensee" is paying "royalties" for the licenses it is receiving in Paragraphs 7 through 10.

(ii) ESI

Complaint Counsel contends that the payment from Schering Plough to ESI was only made to delay generic entry by ESI. This is not a case of a naked payment to delay an entrant who is legally ready and able to compete with Schering because Schering's patent, as discussed supra, is presumed valid. Complaint Counsel introduced a dearth of evidence about the ESI settlement agreement in its case in chief. It introduced fact evidence only in the form of deposition testimony and investigational hearing transcripts of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. Complaint Counsel offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. F. 378. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. F. 380. Thus, no evidence of fair value was offered.

As discussed supra, Complaint Counsel has the burden of proof on all violations alleged in the Complaint. Respondent Schering had no duty or requirement to offer any evidence on the ESI agreement should Complaint Counsel not do so. Complaint Counsel did not present sufficient substantial, reliable evidence to support a conclusion that ESI could have or would have entered the market before the date set on the settlement agreement. Complaint Counsel also did not present sufficient substantial,

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reliable evidence to support a conclusion that the Schering-ESI patent litigation would have settled without the provision for the licensing agreement for enalapril and buspirone being part of that settlement or that any payment was not for fair value. Accordingly, there is no substantial, reliable evidence to conclude that the \$ 15 million was paid only for unlawful delay.

Moreover, it is clear that parties to a patent dispute may exchange consideration to settle this litigation. The Supreme Court has rejected the argument that consideration renders an agreement unlawful. See *Standard Oil Co. v. United States*, 283 U.S. 163, 170-71 n.5 (1931) (noting that the interchange of rights and royalties in a settlement agreement "may promote rather than restrain competition").

d. Complaint Counsel has not demonstrated anticompetitive effects sufficient to shift the burden to Respondents to show procompetitive effects

Once a plaintiff has demonstrated that "great likelihood of anticompetitive effects" from agreements "can easily be ascertained," the burden shifts to a defendant to come forward with plausible procompetitive justifications. *California Dental Ass'n*, 526 U.S. at 770; *NCAA*, 468 U.S. at 113. Because Complaint Counsel has not demonstrated anticompetitive effects, analysis of Respondents' proffered justifications is not necessary.

5. Complaint Counsel Did Not Prove That The "Any Other Sustained Release Microencapsulated Potassium Chloride Tablet" Clause Restricted Competition

Complaint Counsel's position is that the Schering and Upsher-Smith settlement agreement contains additional collateral restraints which are anticompetitive. CCRB at 64. However, Complaint Counsel conceded that parties may settle patent litigation "by an agreement on a date of entry." CCPTB at 43. Any such settlement must necessarily identify the products that are the subject of the agreement--i.e. what the alleged infringer is permitted to market and what the alleged infringer is prohibited

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from marketing under the agreement. F. 168. This degree of specification is necessary in order to limit the alleged infringer's ability to go to market with another infringing product under the agreement. F. 168. It is not enough just to identify the subject of the agreement as "infringing products," as the parties involved in patent litigation necessarily disagree over what does or does not infringe the patent. F. 168. Such a specification would likely lead to renewed litigation, with its attendant costs and inefficiency. Thus, an "ancillary restraint" is ordinarily required to specify the products covered in the agreement by providing an objective description of what can and cannot be marketed prior to the agreed-upon entry date.

Ancillary restraints are permitted if, and precisely because, they are "reasonably necessary" to accomplish a contract's efficiency-enhancing purposes. See *Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) (inquiring whether the challenged conduct is "reasonably necessary to achieve legitimate objectives"); *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367-68 (3d Cir. 1996) (inquiring whether the restraint is "reasonably necessary to achieve the stated objective"); *Rothery Storage*, 792 F.2d at 224 ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.").

The efficiency-enhancing objectives of a patent settlement are clear. *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming."). See also *Schlegel Mfg. Co. v. U.S.M. Corp.*, 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation . . . cannot be overstated.").

Under the Schering/Upsher-Smith settlement, the scope of products subject to the September 1, 2001 entry date agreement was as narrow as was "reasonably necessary" to accomplish the objectives of the settlement. Schering's '743 patent claims a

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"controlled release [microencapsulated] potassium chloride tablet" USX 713 at ESI EXH 000003. The Schering/Upsher-Smith settlement likewise covers any "sustained release microencapsulated potassium chloride tablet" F. 167. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were delayed by the ancillary restraint contained in paragraph 3, nor was such a result intended. F. 170.

Complaint Counsel's witness on this point, Bresnahan, testified that he had "no evidence" that anyone at Schering-Plough or Upsher-Smith had any product other than Klor Con M20 in mind at the time of the agreement. F. 171. With reference to paragraph 3, Bresnahan admitted that he had not examined Upsher-Smith's product pipeline between 1997 and 2001. F. 171.

Complaint Counsel's economist expert, Professor Bresnahan, expressly conceded that, assuming the settlement agreement is otherwise lawful, this provision expanding its coverage to a broader category of products is reasonable. F. 171. Accordingly, Complaint Counsel has failed to prove that the settlement agreement was broader than was "reasonably necessary" to settle the litigation.

6. Complaint Counsel Did Not Prove That the Schering/Upsher-Smith Agreement Had the Effect of Blocking Other Potential Generic Competitors

The Complaint alleges that the June 1997 Settlement Agreement "has the effect of delaying entry into the relevant market by any other potential generic competitor," (Complaint at P66) and specifically identifies only Andrx Corporation as the firm that "cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run." Complaint at P62. Complaint Counsel failed to prove that any potential competitors were blocked or that the exclusivity period was manipulated or even discussed by Schering and Upsher-Smith.

The Complaint only alleges that one specific firm, Andrx, was blocked by Upsher-Smith's exclusivity. Complaint at PP61-62.

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Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx, testified that **[redacted]** F. 395.

Executives at Upsher-Smith were not aware of any other potential competitors blocked from the market. F. 396. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. F. 397.

The 180-day exclusivity period was never discussed between Schering and Upsher-Smith during their settlement negotiations. F. 399. Nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. F. 399. Schering-Plough, similarly, acknowledges that the agreement did not make any reference to exclusivity and the subject was never even discussed. F. 399.

In the absence of proof that any other firm was blocked or that Schering and Upsher-Smith discussed the 180-day exclusivity period in their settlement negotiations, Complaint Counsel has failed to prove that the June 1997 Settlement Agreement unlawfully delayed entry by other potential generic competitors.

F. Third and Fourth Violations of the Complaint

The Third and Fourth Violations of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and ESI to monopolize the relevant markets. Complaint P70, 71. As detailed in Section D, *supra*, to establish monopolization or attempted monopolization, it is necessary to appraise the exclusionary power in terms of the relevant market for the product involved. *Spectrum Sports*, 506 U.S. at 455-56. The relevant market in this case is all

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oral potassium supplements that a physician can prescribe to a patient in need of a potassium supplement.

1. Complaint Counsel Did Not Prove That Schering Had Monopoly Power

Monopoly power is defined "as the power to control prices in the relevant market or to exclude competitors." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 596, n.20 (1985). The critical inquiry is whether Schering had monopoly power in the relevant market at the time it entered the challenged agreements. *Bresnahan*, Tr. 659-60. Complaint Counsel asserts that Schering must have had monopoly power because it otherwise would not have paid Upsher-Smith and ESI not to enter the market. This circular argument is not evidence to support a finding of monopoly power. See *Interpreters*, 123 F.T.C. at 642 (the fact that some members charged the agreed upon price does not necessarily mean that they have market power). Instead, monopoly power is determined through an analysis of market shares, barriers to entry and the ability of rivals to expand output in that market. *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995).

a. Market share

Complaint Counsel presented insufficient evidence on Schering's market share in the market for all oral potassium supplements. Schering's share of the market for potassium supplements between 1995 and 1999 was between 30 and 40 percent. F. 400-04. Schering's market share of less than 50 percent cannot as a matter of law support an inference of monopoly power. See, e.g., *Builey v. Allgas, Inc.*, 284 F.3d 1237, 1250 (11th Cir. 2002) ("A market share at or less than 50% is inadequate as a matter of law to constitute monopoly power"); *Blue Cross & Blue Shield United v. Marshfield Clinic*, 65 F.3d 1406, 1411 (7th Cir. 1995) ("50 percent is below any accepted benchmark for inferring monopoly power from market share").

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b. Lack of barriers to entry and the ability of rivals to expand output

Complaint Counsel did not prove high entry barriers into the market for all oral potassium chloride supplements. The evidence demonstrates that there were over 30 products competing as of 1997 in the potassium chloride market, all of which had entered at some point, and that a number of new competitors entered the market in recent years. F. 405-08. Absent evidence of high entry barriers, an inference of monopoly power is inappropriate. See, e.g., *Western Parcel Express v. [ILLEGIBLE WORD], Inc.*, 190 F.3d 974, 977 (9th Cir. 1999) ("A high market share, though it may ordinarily raise an inference of monopoly power, will not do so in a market with low entry barriers or other evidence of a defendant's inability to control prices or exclude competitors") (citations omitted). Complaint Counsel did not prove the inability of other firms to expand output in the face of a price increase or output reduction by Schering. F. 405-08. When firms can rapidly expand output, as here, an inference of monopoly power is inappropriate. See, e.g., *Rebel Oil Co.*, 51 F.3d at 1441 (power over price "depends largely on the ability of existing firms to quickly increase their own output in response to a contraction by the defendant").

c. Pricing

Contrary to Complaint Counsel's contention, pricing above marginal cost does not establish monopoly power or market power. See *[ILLEGIBLE WORD] Herbert Hovenkamp and Mark A. Lemley, IP and Antitrust § 4.1c*, at 4-5 thru 4-7 (Aspen Law & Business 2002) (use of marginal cost "for measuring power is very hard to make workable in the case of intellectual property"); see *id.* at 4-9 ("the underlying theory of intellectual property rights is that an anticipated stream of above cost prices creates the incentive to engage in research or creativity in the first place") Even if it could, Complaint Counsel failed to prove that K-Dur was sold above marginal cost for extended periods of time. The fact that someone could undersell K-Dur 20 does not prove that contention, and Complaint Counsel offered no other evidence.

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Further, higher prices for a branded product do not establish monopoly power. *SMS Sys. Maintenance Serv., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 17 (1st Cir. 1999) ("In any market with some degree of product differentiation, goods of a single brand will enjoy a certain degree of uniqueness. . . , that fact, without more, does not suffice to establish that the manufacturer enjoys monopoly power in that market."), cert. denied, 528 U.S. 1188 (2000). Evidence of higher prices is ambiguous at best, and insufficient evidence of monopoly power in the absence of market analysis. *Tarrant Serv. Agency v. Am. Standard, Inc.*, 12 F.3d 609, 615 (6th Cir. 1993) (higher prices for genuine parts was not evidence of monopoly power in market that included generic parts).

Complaint Counsel asserts that it proved monopoly power because Schering priced K-Dur 20 at an elevated price. Pricing evidence alone is not sufficient to prove monopoly power. See, e.g., *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) (evidence that firm "routinely charged higher prices than [competitors] while reaping high profits" did not constitute "direct evidence of market power" because there was no evidence of "restricted output"); *Blue Cross & Blue Shield*, 65 F.3d at 1411-12 (higher prices "may reflect a higher quality more costly to provide . . . it is always treacherous to try to infer monopoly power from a high rate of return"); *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 981 (N.D. Cal. 1979), aff'd 698 F.2d 1377 (9th Cir. 1983) ("The inference that a defendant that enjoys healthy profits only does so because of an unhealthy market structure is not a strong one. Good management, superior efficiency and differences in accounting provide explanations that are just as plausible, and none of those explanations is inconsistent with an effectively competitive market."). In this case, as in *Forsyth*, it is conceded by Complaint Counsel that at all times Schering was expanding its output of K-Dur 20. F. 409-13. Also, Schering had no ability to restrict the output of the more than 20 other firms selling "therapeutically equivalent" potassium chloride supplements. F. 408.

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In addition, Complaint Counsel did not prove that Schering's pricing was at a monopoly level. Complaint Counsel's expert witness did not conduct a thorough examination of Schering's prices. Professor Bresnahan did not have a data set of Schering's prices or of competitors pricing; thus he could not compute the relative price level of K-Dur 20 to other products. F. 419 Professor Bresnahan did no study of costs so he is unable to evaluate the price increases for K-Dur 20. F. 423. Professor Bresnahan's failure to study competitive product pricing means that he cannot demonstrate that any price increase of K-Dur 20 over a 5 year period was more or less than the price increases of competitive potassium products. F. 423.

Complaint Counsel also asserts that the failure to lose sales despite a price rise is evidence of a monopoly. This is not sufficient evidence to prove monopoly power. The price of K-Dur 10 rose every time that the price of K-Dur 20 rose. F. 101-03. And K-Dur 10 was at all times more expensive per dose than K-Dur 20. F. 101-03. By this logic, K-Dur 10 should be a "monopoly." Both Professor Bresnahan and Dr. Addanki refused to conclude that K-Dur 10 was a separate "monopoly" unto itself. F. 101-03.

A single firm's price increase data without data from other firms is not helpful. Without knowing systematically what the other firms were doing on price, it is impossible to know the relative price of K-Dur 20 to other firm's products. Nor is it possible to discern if product costs or firm costs are rising. And net pricing considering rebates, allowances and free goods--was also missing from this analysis. These critical aspects of Schering's K-Dur pricing were not studied by Professor Bresnahan. F. 418-29. A strong common feature of K-Dur 10 and K-Dur 20 was the heavy promotion of both products by Schering. F. 80. See Levine, 72 F.3d at 1552 (price increases do not prove actual direct effects without competitors' pricing and costs being examined).

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d. Sensitivity to promotion and advertising

Professor Bresnahan conceded that Schering's advertising increased demand for potassium chloride and in particular K-Dur 20. Ray Russo testified that potassium chloride was highly sensitive to promotions. Schering outspent branded potassium competitors such as Upsher-Smith by more than 100 to 1. F. 427. These levels of advertising were tremendous relative to the size of the potassium marketplace. F. 79-80; Russo, Tr. 3418-19 ("these are relatively I think promotion-sensitive markets. . . . We invested heavily in field force effort . . . we had a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed K-Dur K-Dur 10 and K-Dur 20").

The fact that Schering's sales increased during the 1994 2000 period attests to the power of Schering's detailing and rebate activity. In fact, the approximately \$ 200 million spent by Schering on rebates alone between 1995 and summer 2001 attests to the stiff competition Schering faced prior to the advent of AB-rated substitutes. F. 114-16. Schering also invested millions in promotion. F. 412.

Pharmaceutical promotions are pro-competitive, and Professor Bresnahan testified that aggressive marketing such as that practiced by Schering was not anticompetitive. Yet Professor Bresnahan made no attempt to assess the role of advertising on demand in this case or the relative strength of advertising efforts by potassium firms. Professor Addanki did so and found strong and pronounced effects from Schering's advertising. F. 411-13. Schering's executives recognized that marketing was the key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039). F. 411-13.

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e. K-Dur 10 sales demonstrate that K-Dur 20 was not a monopoly

K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. F. 101. Even if the 10 mEq segment were studied in isolation, K-Dur 10 had less than 9% of new prescriptions of 10 mEq strength potassium chloride. USX 626 at USL 15232 (listing more than 19 10 mEq strength potassium supplements; K-Dur 10 had 8.7% of NRx in 1996). F. 101.

Yet, despite K-Dur 10's non-monopoly status, K-Dur 10 sales performed just as Schering's K-Dur 20 performed. K-Dur 10's sales rose over time due to Schering's promotions. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. F. 101. K-Dur 10 demonstrates that avowedly non-monopoly branded products will perform in exactly the same way that K-Dur 20 performed when it is promoted.

f. Generic potassium products grew at a faster rate than K-Dur 20

Generic potassium--rather than branded potassium--grew at a faster rate than K-Dur 20, demonstrating the price sensitivity of many potassium purchasers. F. 402. Complaint Counsel assert that the sales of K-Dur 20 grew rapidly in the 1997-2000 period, implying that K-Dur 20 outsold all competing potassium despite price increases. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. F. 402. However, at the time relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. F. 402. With K-Dur 20 at 33.0% of total potassium chloride prescriptions, *id.*, other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as

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of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. F. 402.

2. Complaint Counsel Did Not Prove the Requisite Specific Intent for a Conspiracy to Monopolize the Market for Potassium Supplements

"Specific intent to monopolize is the heart of a conspiracy charge." *Salco Corp. v. Gen. Motors Corp.*, 517 F.2d 567, 576 (10th Cir. 1975). It is more demanding than the general-intent requirement of Section 1 claims. See, e.g., *Wagner v. Magellan Health Servs., Inc.*, 121 F. Supp. 2d 673, 681 (N.D. Ill. 2000) ("A conspiracy to monopolize under Section 2 is somewhat different than its Section 1 counterpart because of its heightened intent element, i.e., concerted action by knowing participants who have a specific intent to achieve a monopoly"). As one court recently stated, specific intent "signifies something more than willing, voluntary, and knowing participation in the illegal course of conduct that [defendant] is alleged to have pursued." *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 728, 731 (D. Md. 2001). Rather, "it means participating in that course of conduct for the specific, shared purpose of maintaining" Schering's monopoly. *Id.* (citation omitted).

A mere confluence of economic interests between the parties does not establish a specific intent to monopolize. See *Building Indus. Fund v. Local Union No. 3*, 992 F. Supp. 162, 186 (D.D.N.Y. 1996) ("The essence of a conspiracy is not simply a commonality of interest. It involves an agreement by two or more people to accomplish a specific illegal objective"); *Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 422 (D.D.C. 1988) (rejecting theory that "mutual purposes and intended effects" could satisfy specific intent standard) (citation omitted).

There is insufficient evidence to demonstrate that Upsher-Smith or Schering "specifically intended" to further Schering's alleged unlawful monopoly in the sale of K-Dur 20. Moreover, there were numerous legitimate business justifications offered for Upsher-Smith's and Schering's conduct, including ending the

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expensive and acrimonious patent litigation, obtaining a date certain for entry of Upsher-Smith's generic product five years before the expiration of Schering's patent, opening the door for other generic mEq sustained-release potassium chloride supplements to enter the market, freeing up resources at Upsher-Smith for future pharmaceutical R&D and marketing of potassium products; and giving Upsher-Smith overseas distribution capability for six of its pharmaceutical products.

As the court in *Microsoft* explained, to establish a Section 2 conspiracy, "what plaintiffs must prove is that when confronted with Microsoft's demands, the OEM defendants stepped back and concluded that maintaining Microsoft's monopolies was a goal that they themselves desired to accomplish." *Microsoft*, 127 F. Supp. 2d at 731. The credible evidence demonstrates that far from seeking to further Schering's alleged monopoly, Upsher-Smith fought hard to bring its product to market and competed vigorously with Schering before, during and after the execution of the settlement agreement.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith").

2. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission, 15 U.S.C. § 44.

4. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

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5. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

6. Complaint Counsel bears the burden of proof of establishing each element of the violations of the Complaint.

7. The relevant geographic market for assessing the allegations of the Complaint is the United States.

8. The relevant product market for assessing the allegations of the Complaint is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement.

9. Complaint Counsel failed to prove or properly define the relevant product market.

10. Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others--for example, by the initiation of infringement litigation--from manufacturing, using and/or selling the invention during the patent term.

11. The agreement between Schering Plough and Upsher-Smith did not unreasonably restrain competition and was not an unfair method of trade.

12. The agreement between Schering Plough and ESI did not unreasonably restrain competition and was not an unfair method of trade.

13. Schering-Plough does not have monopoly power in the relevant product market.

14. Schering-Plough did not engage in conduct to unlawfully preserve monopoly power in the relevant product market.

Initial Decision

15. Schering-Plough did not conspire with Upsher-Smith or ESI to unlawfully preserve monopoly power in the relevant product market.

16. Complaint Counsel failed to meet its burden of proof in support of the Violations alleged in the Complaint.

17. The Complaint should be and is dismissed.

ORDER

For the reasons stated above,

IT IS ORDERED that all violations of the Complaint be, and hereby are, dismissed.

Complaint

IN THE MATTER OF**GENCORP INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4099; File No. 0310152

Complaint, October 14, 2003--Decision, December 19, 2003

This consent order addresses the acquisition by Respondent GenCorp Inc. -- a technology-based manufacturing company with businesses concentrated in aerospace and defense, fine chemicals and automotive products -- of the propulsion business of Atlantic Research Corporation, a subsidiary of Sequa Corporation. The order, among other things, requires the respondent to divest the in-space liquid propulsion business of Atlantic Research Corporation -- including its Niagara and Westcott production facilities, specialized manufacturing and testing equipment, customer lists, intellectual property and other assets -- to a Commission-approved acquirer, within six months and at no minimum price. An accompanying Order to Hold Separate and Maintain Assets requires the respondent to preserve the Atlantic Research Corporation in-space liquid propulsion business as a viable, competitive, and ongoing operation until the divestiture is achieved., and includes provisions designed to ensure that no material confidential information is exchanged between GenCorp and the ARC in-space liquid propulsion business.

Participants

For the Commission: *Jonathan S. Klarfeld, James E. Southworth, Sean G. Dillon, Michael R. Barnett, Sylvia M. Brooks, Robert R. Pickett, Steven K. Bernstein, Michael R. Moiseyev, Naomi Licker, Daniel P. Ducore, Abraham L. Wickelgren, Charissa P. Wellford and Mary T. Coleman.*

For the Respondent: *Tom D. Smith, Mia F. Cohen, and Courtney M. Schaberg, Jones Day.*

COMPLAINT

Pursuant to the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission ("Commission"), having reason to

Complaint

believe that Respondent GenCorp Inc. (“GenCorp”), a corporation subject to the jurisdiction of the Commission, has entered into an agreement whereby GenCorp would acquire certain assets of Atlantic Research Corporation (“ARC”), a subsidiary of Sequa Corporation (“Sequa”), in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent GenCorp Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio, with its office and principal place of business located at Highway 50 and Aerojet Road, Rancho Cordova, California 95670.
2. Respondent GenCorp is engaged in, among other things, the research, development, manufacture and sale of in-space liquid propulsion thrusters, including monopropellant, bipropellant apogee, dual mode apogee, and bipropellant attitude control thrusters.
3. Respondent is, and at all times herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. On or about May 2, 2003, GenCorp’s Aerojet-General Corporation (“Aerojet”) subsidiary entered into a Purchase Agreement, as subsequently amended August 29, 2003 (“Agreement”), to acquire substantially all of the assets of Sequa’s

Complaint

ARC subsidiary as well as the shares of ARC UK Limited (“Acquisition”). The ARC airbag inflator business is not included in the sale to Aerojet. Under the terms of the Agreement, the Acquisition is valued at approximately \$133 million.

III. THE RELEVANT MARKETS

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are:

a. the research, development, manufacture and sale of monopropellant thrusters, a type of in-space propulsion thruster that utilizes a single liquid fuel source, typically hydrazine, and is used primarily to perform attitude control and station-keeping maneuvers on spacecraft;

b. the research, development, manufacture and sale of bipropellant apogee thrusters, a type of in-space propulsion thruster that utilizes a liquid fuel, typically monomethylhydrazine, in combination with an oxidizer and is used primarily to perform apogee maneuvers on spacecraft;

c. the research, development, manufacture and sale of dual mode apogee thrusters, a type of in-space propulsion thruster that utilizes hydrazine in combination with an oxidizer and is used primarily to perform apogee maneuvers on spacecraft; and

d. the research, development, manufacture and sale of bipropellant attitude control thrusters, a type of in-space propulsion thruster that utilizes a liquid fuel, typically monomethylhydrazine, in combination with an oxidizer and is used primarily to perform attitude control and station-keeping maneuvers on spacecraft.

6. For the purposes of this Complaint, the United States is the relevant geographic market in which to analyze the effects of the Acquisition in the relevant line of commerce. Foreign suppliers of

Complaint

in-space propulsion thrusters are not effective competitors to supply the relevant products to most U.S. in-space propulsion customers for a number of reasons, most notably U.S. export regulations, and, for many Department of Defense programs, national security issues.

IV. THE STRUCTURE OF THE MARKETS

7. The U.S. markets for the research, development, manufacture and sale of monopropellant, bipropellant apogee and dual mode apogee thrusters are extremely highly concentrated, as measured by the Herfindahl-Hirschman Index (“HHI”). Aerojet and ARC are the only two significant suppliers of monopropellant, bipropellant apogee and dual mode apogee thrusters in the U.S. market and each other’s closest competitor. The proposed acquisition, if consummated, would result in a near monopoly in each of these relevant markets.

8. The market for the research, development, manufacture and sale of bipropellant attitude control thrusters is highly concentrated as measured by the HHI. ARC is the leading supplier of bipropellant attitude control thrusters in the United States. For many customers, including the vast majority of U.S. governmental customers, ARC essentially has a monopoly position in this market. Although Aerojet does not currently produce bipropellant attitude control thrusters, it has substantial existing expertise in this area, has produced these thrusters in the recent past and is a likely potential entrant into this market. The proposed acquisition, if consummated, would eliminate the most likely and effective potential competitor in this market.

V. ENTRY CONDITIONS

9. Entry into each of the relevant markets is a difficult process because of, among other things, the time and cost associated with researching and developing in-space propulsion thrusters, acquiring the necessary production assets, developing the expertise needed to successfully design, produce, and test these

Complaint

products, as well as developing heritage (i.e., actual flight time in space) for these products.

10. New entry into any of the relevant markets, other than Aerojet's potential entry into the research, development, manufacture and sale of bipropellant attitude control thrusters, is not likely to occur to deter or counteract the adverse competitive effects described in Paragraph 12 because the costs of entry are extremely high relative to the potential sales opportunities available to an entrant.

11. New entry into any of the relevant markets, other than Aerojet's potential entry into the research, development, manufacture and sale of bipropellant attitude control thrusters, would not occur in a timely manner to deter or counteract the adverse competitive effects described in Paragraph 12 because it would take over two years for an entrant to accomplish the steps required for entry and to achieve a significant market impact.

VI. EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Aerojet and ARC in the relevant markets for the research, development, manufacture and sale of monopropellant, bipropellant apogee and dual mode apogee thrusters, thereby:
 - (i) creating a virtual monopoly in each of these relevant markets;

Complaint

(ii) substantially increasing the likelihood that Aerojet will unilaterally exercise market power in each of these relevant markets;

(iii) reducing current incentives to improve service or product quality, or pursue further innovation in each of these relevant markets; and

(iv) increasing the likelihood that U.S. commercial, civil and defense customers would be forced to pay higher prices for monopropellant, bipropellant apogee and dual mode apogee thrusters; and

b. by eliminating actual potential competition between Aerojet and ARC in the market for the research, development, manufacture and sale of bipropellant attitude control thrusters, thereby:

(i) increasing the likelihood that U.S. commercial, civil and defense customers would be forced to pay higher prices in the future for bipropellant attitude control thrusters than they otherwise would have; and

(ii) reducing future incentives to improve service or product quality, or pursue further innovation in this market.

VII. VIOLATIONS CHARGED

13. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

Complaint

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fourteenth day of October, 2003, issues its Complaint against said Respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent GenCorp Inc. (“GenCorp”) of certain assets of Atlantic Research Corporation (“ARC”), a subsidiary of Sequa Corporation, and Respondent having been furnished thereafter with a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets (“Hold Separate”) and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent GenCorp Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio, with its office and principal place of business located at Highway 50 and Aerojet Road, Rancho Cordova, CA 95670.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. "GenCorp" or "Respondent" means GenCorp Inc., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by GenCorp, including but not limited to Aerojet-General Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Acquirer" means the Person who acquires the ARC In-Space Liquid Propulsion Assets pursuant to Paragraph II or III of this Order.
- C. "Acquisition" means the proposed acquisition of certain assets of ARC by GenCorp, as described in the Purchase Agreement by and between Atlantic Research Corporation and Aerojet-General Corporation dated May 2, 2003, and as amended August 29, 2003.
- D. "ARC" means Atlantic Research Corporation, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal

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place of business located at 5945 Wellington Road, Gainesville, VA 20155, and its subsidiaries, divisions, groups and affiliates controlled by ARC, including, but not limited to, ARC UK Limited (“ARC-UK”).

- E. “ARC In-Space Liquid Propulsion Assets” means all assets of ARC, whether tangible or intangible, acquired by Respondent from ARC in the Acquisition and relating to the ARC In-Space Liquid Propulsion Business including, but not limited to:
1. the Niagara Falls Facility;
 2. the Westcott Facility;
 3. all accounts and notes receivable and other claims for money due to Respondent, relating to the Business, as the same exist on the Effective Date of Divestiture;
 4. all raw materials, works in process, supplies, spare parts and finished goods inventories relating to the Business, as the same exist on the Effective Date of Divestiture;
 5. all contracts, agreements, commitments (including pending bids and proposals) and instruments to which Respondent is a party relating to the Business as of the Effective Date of Divestiture, all unfulfilled orders outstanding as of the Effective Date of Divestiture for the purchase of raw materials, goods or services by Respondent relating to the Business, and all unfulfilled orders outstanding as of the Effective Date of Divestiture for the sale of goods or services provided by the Business;
 6. all machinery, equipment, tools, dies, test equipment, furniture, fixtures, vehicles and other personal property owned or leased by Respondent relating to the Business as of the Effective Date of Divestiture, and, to the extent of Respondent’s interest therein, all machinery and equipment

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relating to the Business, which is owned and/or furnished by any domestic or foreign governmental entity;

7. all patents, patent applications, licenses, trademarks, trade names, domain names, computer software, data, copyrights, documentation, know-how, goodwill, trade secrets, confidential business information (including formulas, compositions, inventions and manufacturing and production processes and techniques, drawings, designs, technical data, customer and supplier data, pricing and cost information), all results and other information related to any research and development project, in each of the foregoing cases owned or licensed by Respondent and relating to the Business, and all other intellectual property rights (in whatever form or medium), to the extent of Respondent's interest therein, relating to the Business as of the Effective Date of Divestiture; *provided, however*, that nothing in this paragraph shall require any Person to relinquish the exclusive right to use the name "Atlantic Research Corporation" or "ARC"; *provided further*, however, that any Acquirer shall have the exclusive right to represent itself as carrying on any business relating to the ARC In-Space Liquid Propulsion Assets in continuation thereof as a going concern and all of the goodwill associated therewith;
8. to the extent legally transferrable, all customer and government approvals, consents, licenses, permits, waivers, or other authorizations, held by Respondent and relating to the Business as of the Effective Date of Divestiture;
9. all books, records, ledgers, files, documents, correspondence, lists, plats, specifications, surveys, invoices, customer and supplier lists, drawings, creative materials, advertising and promotional materials, studies, reports and other materials (in whatever form or medium) owned by Respondent as of the Effective Date of Divestiture, in each case to the extent that they relate to the

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Business;

10. all real property owned or leased by Respondent relating to the Business as of the Effective Date of Divestiture, together with all buildings, structures, improvements, fixtures and fittings located on or attached to such real property, and all rights, privileges, easements and other appurtenances belonging thereto; and
 11. all warranties and guarantees, express or implied, relating to the Business as of the Effective Date of Divestiture; provided, however, that ARC In-Space Liquid Propulsion Assets does not include: Hydrazine Actuation Systems; solid/gel side thrust and attitude control propulsion systems, spin motors, high precision motors and gas generators; solid upper stage ejection rocket motors; and all assets, tangible or intangible, primarily related thereto; information systems equipment and applications, including but not limited to computer hardware and software programs, not physically located at the facilities of the ARC In-Space Liquid Propulsion Business but shared with the Business through local and/or wide area networking systems; and telecommunications systems equipment and applications, not physically located at the facilities of the ARC In-Space Liquid Propulsion Business but shared with the Business through local and/or wide area telecommunications systems.
- F. “ARC In-Space Liquid Propulsion Business” or “Business” means the ARC and ARC-UK business engaged in the research, design, development, manufacture, fabrication, assembly, marketing, distribution, sale or service of In-Space Liquid Propulsion Products.
- G. “ARC In-Space Liquid Propulsion Business Employees” means all full-time, part-time, or contract employees whose duties primarily relate to the Business or have primarily

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related to the Business at any time during the period commencing twelve months prior to the Effective Date of Divestiture.

- H. “ARC In-Space Liquid Propulsion Business Key Employees” means those ARC In-Space Liquid Propulsion Business Employees identified in Confidential Appendix A attached to this Order.
- I. “ARC In-Space Liquid Propulsion Hold Separate Employees” means all full-time, part-time, or contract employees whose duties primarily relate to the Business during the Hold Separate Period.
- J. “Commission” means the Federal Trade Commission.
- K. “Effective Date of Divestiture” means the date on which the applicable divestiture of the ARC In-Space Liquid Propulsion Assets occurs.
- L. “Hold Separate Period” means the time period during which the Hold Separate is in effect, which shall begin as of the date the Acquisition occurs and terminate pursuant to Paragraph V of the Hold Separate.
- M. “In-Space Liquid Propulsion Products” means monopropellant, bipropellant and dual mode thrusters, systems thereof, and propellant tanks, for use on satellites and spacecraft.
- N. “Niagara Falls Facility” means the facility that relates to the ARC In-Space Liquid Propulsion Business and that is located at 6686 Walmore Road, Niagara Falls, NY 14303, and all of Respondent’s interests in all assets, whether tangible or intangible, relating to the facility.

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- O. "Person" means any individual, partnership, firm, trust, association, corporation, joint venture, unincorporated organization, or other business or governmental entity.
- P. "Westcott Facility" means the facility that relates to the ARC In-Space Liquid Propulsion Business and that is located at Westcott Metro Park, Westcott Aylesbury Buckinghamshire HP180NZ, England, and all of Respondent's interests in all assets, whether tangible or intangible, relating to the facility.

II.

IT IS FURTHER ORDERED that:

- A. Respondent shall divest, within six (6) months after the Acquisition occurs, the ARC In-Space Liquid Propulsion Assets to a single Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission, absolutely and in good faith and at no minimum price.
- B. Respondent shall:
1. not later than forty-five (45) days before the Effective Date of Divestiture, (a) provide to the Acquirer a list of all ARC In-Space Liquid Propulsion Business Employees and ARC In-Space Liquid Propulsion Business Key Employees; (b) allow the Acquirer to interview any ARC In-Space Liquid Propulsion Business Employees; and (c) in compliance with all laws, allow the Acquirer to inspect the personnel files and other documentation relating to such ARC In-Space Liquid Propulsion Business Employees;
 2. not later than thirty (30) days before the Effective Date of Divestiture, provide an opportunity for the Acquirer, (a) to meet personally, and outside the presence or hearing of any employee or agent of Respondent, with any one or

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more of the ARC In-Space Liquid Propulsion Business Employees; and (b) to make offers of employment to any one or more of the ARC In-Space Liquid Propulsion Business Employees;

3. (a) not directly or indirectly interfere with the Acquirer's offer of employment to any one or more of the ARC In-Space Liquid Propulsion Business Employees, not directly or indirectly attempt to persuade any one or more of the ARC In-Space Liquid Propulsion Business Employees to decline any offer of employment from the Acquirer, and not offer any incentive to any ARC In-Space Liquid Propulsion Business Employees to decline employment with the Acquirer;

(b) irrevocably waive any legal or equitable right to deter any ARC In-Space Liquid Propulsion Business Employee from accepting employment with the Acquirer, including, but not limited to, waiving any non-compete or confidentiality provisions of employment or other contracts with Respondent that relate to the In-Space Liquid Propulsion Products;

(c) not interfere with the employment by the Acquirer of any ARC In-Space Liquid Propulsion Business Employee; and

(d) continue employee benefits to ARC In-Space Liquid Propulsion Hold Separate Employees until the Effective Date of Divestiture consistent with the requirements of the Purchase Agreement by and between Atlantic Research Corporation and Aerojet-General Corporation dated May 2, 2003, and as amended August 29, 2003, including regularly scheduled or merit raises and bonuses, regularly scheduled vesting of all pension benefits, and reimbursement of relocation expenses;

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4. provide a retention incentive bonus to ARC In-Space Liquid Propulsion Business Key Employees, who accept employment with the Commission-approved Acquirer, equal to ten (10) percent of such employee's annual salary under the following terms: (a) five (5) percent of the incentive to be paid upon the employee's completion of six (6) months of continuous employment with the Commission-approved Acquirer after the Effective Date of Divestiture; and (b) the remaining five (5) percent to be paid upon the employee's completion of one (1) year of continuous employment with the Commission-approved Acquirer after the Effective Date of Divestiture;

5. subject to the provisions of Paragraph II.B.6. below, for a period of one (1) year from the Effective Date of Divestiture, not, directly or indirectly, solicit, induce, or attempt to solicit or induce any ARC In-Space Liquid Propulsion Business Employees who have accepted offers of employment with the Acquirer to terminate their employment relationship with the Acquirer; *provided, however*, a violation of this provision will not occur if: (1) the individual's employment has been terminated by the Acquirer, (2) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (3) Respondent hires employees who apply for employment with Respondent, as long as such employees were not solicited by Respondent in violation of this paragraph; and

6. notwithstanding the provisions of Paragraph II.B.5. above, for a period of six months from the Effective Date of Divestiture, not employ or offer to employ any ARC In-Space Liquid Propulsion Business Employees who have accepted offers of employment with the Acquirer unless any such individual's employment has been terminated by the Acquirer.

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C. In the event that Respondent is unable to satisfy all conditions necessary to divest any intangible asset that is a permit, license or right granted by any domestic or foreign governmental entity, Respondent shall provide such assistance as the Acquirer may reasonably request in the Acquirer's efforts to obtain a comparable permit, license or right.

D. The purpose of the divestiture of the ARC In-Space Liquid Propulsion Assets, and of the other provisions of this paragraph, is to ensure the continued operation of the ARC In-Space Liquid Propulsion Business as a viable, on-going business by a firm that has the ability and incentive to invest and compete in the research, design, development, manufacture, fabrication, assembly, marketing, distribution, sale and service of In-Space Liquid Propulsion Products, and to remedy the lessening of competition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

A. If Respondent has not, within the time period required, complied with the requirements of Paragraph II, absolutely and in good faith, the Commission may appoint a Trustee to effectuate the divestiture required by Paragraph II, consistent with the purpose stated in Paragraph II.D.

B. In the event that the Commission or the United States Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Trustee in such action. Neither the appointment of a Trustee nor a decision not to appoint a Trustee under this paragraph shall preclude the Commission or the United States Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed

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Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this Order.

C. If a Trustee is appointed by the Commission or a court pursuant to Paragraph III.A or III.B of this Order, Respondent shall consent to the following terms and conditions regarding the Trustee's powers, duties, authority, and responsibilities:

1. the Commission shall select the Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Trustee, Respondent shall be deemed to have consented to the selection of the proposed Trustee;
2. subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to divest the ARC In-Space Liquid Propulsion Business, assign the agreements required to be assigned, and enter into the required agreements, thereby binding Respondent, all on such terms and conditions as are necessary to comply with the requirements of the applicable paragraph, to comply with all applicable laws, and to effectuate the remedial purposes of this Order;
3. within ten (10) days after appointment of the Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Trustee, of the court, transfers to the Trustee all rights and powers necessary to permit

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the Trustee to effect the divestiture required by this Order;

4. the Trustee shall have six (6) months from the date the Commission approves the trust agreement described in Paragraph III.C.3 to accomplish the divestiture to an Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission. If, however, at the end of the six-month period, the Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission or, in the case of a court-appointed Trustee, by the court;
5. subject to all applicable laws and regulations, the Trustee shall have full and complete access to the personnel, books, records and facilities related to the ARC In-Space Liquid Propulsion Business or to any other relevant information, as the Trustee may request. Respondent shall develop such financial or other information as the Trustee may request and shall cooperate with the Trustee. Respondent shall take no action to interfere with or impede the Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Trustee, by the court;
6. the Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Trustee receives bona fide offers from more than

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one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such entity within five (5) business days of receiving notification of the Commission's approval;

7. the Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Trustee's duties and responsibilities. The Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Trustee, by the court, of the account of the Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondent, and the Trustee's power shall be terminated. The Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Trustee's divesting the assets to be divested;
8. Respondent shall indemnify the Trustee and hold the Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims,

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damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts or omissions, or bad faith by the Trustee or his or her agents;

9. if the Commission determines that the Trustee has ceased to act or failed to act diligently, a substitute Trustee shall be appointed in the same manner as provided in Paragraph III of this Order;
10. the Commission or, in the case of a court-appointed Trustee, the court, may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order;
11. the Trustee shall have no obligation or authority to operate or maintain the assets required to be divested by this Order;
12. the Trustee shall report in writing to Respondent and the Commission every sixty (60) days concerning the Trustee's efforts to accomplish the divestiture; and
13. Respondent may require the Trustee to sign a confidentiality agreement; *provided, however*, such agreement shall not restrict the Trustee from providing any information to the Commission.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order becomes final and every thirty (30) days thereafter until Respondent has fully complied with the provisions of Paragraphs II and III of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Order. Respondent shall include in its

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compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order, including a description of all substantive contacts or negotiations for the divestiture and the identity of all parties contacted. Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent made to its principal United States offices, Respondent shall permit any duly authorized representative of the Commission:

A. Access, during office hours of Respondent and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent relating to any matters contained in this Order; and

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B. Upon five (5) days' notice to Respondent and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondent, who may have counsel present, regarding any such matters.

By the Commission.

Confidential Appendix A

[Redacted From Public Record Version]

Order

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent GenCorp Inc. (“GenCorp”) of certain assets of Atlantic Research Corporation (“ARC”), a subsidiary of Sequa Corporation, and Respondent having been furnished thereafter with a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Agreement Containing Consent Orders and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets (“Hold Separate”):

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1. Respondent GenCorp is a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio, with its office and principal place of business located at Highway 50 and Aerojet Road, Rancho Cordova, CA 95670.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

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I.

IT IS ORDERED that, as used in this Hold Separate, the following definitions and provisions shall apply:

- A. "GenCorp" or "Respondent" means GenCorp Inc., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by GenCorp, including but not limited to Aerojet-General Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Acquirer" has the same definition as the term does in the Decision and Order.
- C. "Acquisition" means the proposed acquisition of certain assets of ARC by GenCorp, as described in the Purchase Agreement by and between Atlantic Research Corporation and Aerojet-General Corporation dated May 2, 2003, and as amended August 29, 2003.
- D. "ARC" means Atlantic Research Corporation, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and

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principal place of business located at 5945 Wellington Road, Gainesville, VA 20155, and its subsidiaries, divisions, groups and affiliates controlled by ARC, including, but not limited to, ARC UK Limited (“ARC-UK”).

- E. “ARC In-Space Liquid Propulsion Business” or “Business” means the ARC and ARC-UK business engaged in the research, design, development, manufacture, fabrication, assembly, marketing, distribution, sale, or service of In-Space Liquid Propulsion Products.
- F. “ARC In-Space Liquid Propulsion Business Employees” means all full-time, part-time, or contract employees whose duties primarily relate to the Business or have primarily related to the Business at any time during the period commencing twelve months prior to the Effective Date of Divestiture.
- G. “ARC In-Space Liquid Propulsion Business Key Employees” means those ARC In-Space Liquid Propulsion Business Employees identified in Confidential Appendix A attached hereto.
- H. “ARC In-Space Liquid Propulsion Hold Separate Employees” means all full-time, part-time, or contract employees whose duties primarily relate to the Business during the Hold Separate Period.
- I. "Commission" means the Federal Trade Commission.
- J. “Decision and Order” means:
 - 1. until the issuance and service of a final Decision and Order by the Commission, the proposed Decision and Order contained in the Consent Agreement in this matter;
and

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2. following the issuance and service of a final Decision and Order by the Commission, the final Decision and Order issued by the Commission.
- K. "Effective Date of Divestiture" means the date on which the divestiture required by the Decision and Order occurs.
- L. "Held Separate Business" means the ARC In-Space Liquid Propulsion Business and all ARC In-Space Liquid Propulsion Hold Separate Employees.
- M. "Hold Separate Period" means the time period during which the Hold Separate is in effect, which shall begin as of the date the Acquisition occurs and terminate pursuant to Paragraph V hereof.
- N. "Hold Separate Trustee" means the individual appointed to act as the Hold Separate Trustee pursuant to Paragraph II.D. hereof.
- O. "In-Space Liquid Propulsion Products" means monopropellant, bipropellant and dual mode thrusters, systems thereof, and propellant tanks, for use on satellites and spacecraft.
- P. "Material Confidential Information" means competitively sensitive or proprietary information including, but not limited to, all customer lists, price lists, marketing methods, patents, technologies, processes, or other trade secrets; *provided, however*, Material Confidential Information does not include information in the public domain or independently known to a Person from sources other than the Person to which the information pertains.
- Q. "Person" means any individual, partnership, firm, trust, association, corporation, joint venture, unincorporated organization, or other business or governmental entity.

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II.

IT IS FURTHER ORDERED that:

- A. During the Hold Separate Period, Respondent shall hold the Held Separate Business separate, apart, and independent as required by this Hold Separate and shall vest the Held Separate Business with all rights, powers, and authority necessary to conduct its business; Respondent shall not exercise direction or control over, or influence directly or indirectly, the Held Separate Business or any of its operations, or the Hold Separate Trustee, except to the extent that Respondent must exercise direction and control over the Held Separate Business as is necessary to assure compliance with this Hold Separate, the Decision and Order, and all applicable laws.
- B. Respondent shall:
1. During the Hold Separate Period, take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Held Separate Business to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear; and
 2. From the date Respondent executes the Agreement containing Consent Orders until the Hold Separate Period begins, take such actions as are necessary to assure that ARC maintains the viability, marketability, and competitiveness of the Held Separate Business to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear.
- C. The purpose of this Hold Separate is to: (1) preserve the Held Separate Business as a viable, competitive, and ongoing business independent of Respondent until the

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divestiture required by the Decision and Order is achieved; (2) assure that no Material Confidential Information is exchanged between Respondent and the Held Separate Business, except in accordance with the provisions of this Hold Separate; and (3) prevent interim harm to competition pending the relevant divestiture and other relief.

D. Respondent shall hold the Held Separate Business separate, apart, and independent on the following terms and conditions:

1. Charles L. Wilkins of KPMG LLP, shall serve as Hold Separate Trustee, pursuant to the agreement executed by the Hold Separate Trustee and Respondent and attached as Confidential Appendix B to this Hold Separate (“Trustee Agreement”).
 - a. The Trustee Agreement shall require that, no later than five (5) days after this Hold Separate becomes final, Respondent shall transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate and consistent with the purposes of the Decision and Order.
 - b. No later than five (5) days after this Hold Separate becomes final, Respondent shall, pursuant to the Trustee Agreement, transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate and consistent with the purposes of the Decision and Order.
 - c. The Hold Separate Trustee shall have the responsibility, consistent with the terms of this Hold Separate and the Decision and Order, for monitoring

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the organization of the Held Separate Business; for managing the Held Separate Business through the Manager; for maintaining the independence of the Held Separate Business; and for monitoring Respondent's compliance with its obligations pursuant to this Hold Separate and the Decision and Order.

- d. Subject to all applicable laws and regulations, the Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents and facilities of the Held Separate Business or to any other relevant information as the Hold Separate Trustee may reasonably request, including, but not limited to, all documents and records kept by Respondent in the ordinary course of business that relate to the Held Separate Business. Respondent shall develop such financial or other information as the Hold Separate Trustee may reasonably request and shall cooperate with the Hold Separate Trustee. Respondent shall take no action to interfere with or impede the Hold Separate Trustee's ability to monitor Respondent's compliance with this Hold Separate and the Decision and Order or otherwise to perform his/her duties and responsibilities consistent with the terms of this Hold Separate.
- e. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
- f. The Commission may require the Hold Separate Trustee to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with

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performance of the Hold Separate Trustee's duties.

- g. Respondent may require the Hold Separate Trustee to sign an appropriate confidentiality agreement prohibiting the disclosure of any Material Confidential Information gained as a result of his/her role as Hold Separate Trustee to anyone other than the Commission.
- h. Thirty (30) days after the Hold Separate becomes final, and every thirty (30) days thereafter until the Hold Separate terminates, the Hold Separate Trustee shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate. Included within that report shall be the Hold Separate Trustee's assessment of the extent to which the Held Separate Business is meeting (or exceeding) its projected goals as are reflected in operating plans, budgets, projections or any other regularly prepared financial statements.
- i. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Commission may appoint a substitute Hold Separate Trustee consistent with the terms of this paragraph, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Hold Separate Trustee within five (5) days after notice by the staff of the Commission to Respondent of the identity of any substitute Hold Separate Trustee, Respondent shall be deemed to have consented to the selection of the proposed substitute trustee. Respondent and the substitute Hold Separate Trustee shall execute a trustee agreement, subject to the approval of the Commission, consistent with this paragraph.

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2. No later than one (1) day after the Acquisition is consummated, Respondent shall enter into a management agreement with, and transfer all rights, powers, and authorities necessary to manage and maintain the Held Separate Business to Robert A. Huebner (“Manager”).
 - a. In the event that Robert A. Huebner ceases to act as Manager, then Respondent shall select a substitute Manager, subject to the approval of the Commission, and transfer to the substitute Manager all rights, powers, and authorities necessary to permit the substitute Manager to perform his/her duties and responsibilities, pursuant to this Hold Separate.
 - b. The Manager shall report directly and exclusively to the Hold Separate Trustee and shall manage the Held Separate Business independently of the management of Respondent. The Manager shall not be involved, in any way, in the operations of the other businesses of Respondent during the term of this Hold Separate.
 - c. The Manager shall have no financial interests affected by Respondent’s revenues, profits or profit margins, except that the Manager’s compensation for managing the Held Separate Business may include economic incentives dependent on the financial performance of the Held Separate Business if there are also sufficient incentives for the Manager to operate the Held Separate Business at no less than current rates of operation (including, but not limited to, current rates of production and sales) and to achieve the objectives of this Hold Separate.
 - d. The Manager shall make no material changes in the present operation of the Held Separate Business except with the approval of the Hold Separate Trustee, in consultation with the Commission.

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- e. The Manager shall have the authority, with the approval of the Hold Separate Trustee, to remove employees of the Held Separate Business and replace them with others of similar experience or skills. If any Person ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Manager, in consultation with the Hold Separate Trustee, may request Respondent to, and Respondent shall, appoint a substitute Person, which Person the Manager shall have the right to approve.
 - f. In addition to ARC In-Space Liquid Propulsion Business Employees employed as of the date the Consent Agreement is signed by Respondent, the Manager may employ such Persons as are reasonably necessary to assist the Manager in managing the Held Separate Business.
 - g. The Hold Separate Trustee shall be permitted, in consultation with the Commission staff, to remove the Manager for cause. Within fifteen (15) days after such removal of the Manager, Respondent shall appoint a replacement Manager, subject to the approval of the Commission, on the same terms and conditions as provided in Paragraph II.D.2 of this Hold Separate.
3. The Held Separate Business shall be staffed with sufficient employees to maintain the viability, marketability, and competitiveness of the Held Separate Business. To the extent that any employees of the Held Separate Business leave or have left the Held Separate Business prior to the Effective Date of Divestiture, the Manager, with the approval of the Hold Separate Trustee, may replace departing or departed employees with Persons who have similar experience and expertise or determine not to replace such departing or departed employees.

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4. In connection with support services not included within the Held Separate Business that are being provided by Respondent or ARC or which Respondent or ARC has contracted to provide to the Held Separate Business by third parties, Respondent shall continue to provide or contract to provide, or offer to provide or contract to provide, the same support services to the Held Separate Business as are being provided to the Held Separate Business by Respondent, ARC, or third parties as of the date the Consent Agreement is signed by Respondent. For services that Respondent or ARC previously provided to the Held Separate Business, Respondent may charge the same fees, if any, charged by Respondent or ARC for such support services as of the date the Consent Agreement is signed by Respondent. For any other services or products that Respondent may provide the Held Separate Business, Respondent may charge no more than the same price it charges others for the same services or products. Respondent's personnel providing such services or products must retain and maintain all Material Confidential Information of the Held Separate Business on a confidential basis, and, except as is permitted by this Hold Separate, such Persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any Person whose employment relates to any of Respondent's businesses, other than the Held Separate Business. Such personnel who have or may have access to Material Confidential Information shall also execute confidentiality agreements prohibiting the disclosure of any Material Confidential Information of the Held Separate Business.
 - a. Respondent shall offer to the Held Separate Business any services that Respondent provides to its other businesses directly or through third party contracts, or that it or ARC has provided directly or through third

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party contracts to the ARC In-Space Liquid Propulsion Business at any time since January 1, 2002. The Held Separate Business may, at the option of the Manager with the approval of the Hold Separate Trustee, obtain such services and products from Respondent. The services that Respondent shall offer the Held Separate Business shall include, but shall not be limited to, the following:

- (1) federal and state regulatory policy development and compliance;
 - (2) human resources and administrative services, including, but not limited to, procurement and administration of employee benefits;
 - (3) environmental health and safety services, including, but not limited to, services to develop corporate policies and insure compliance with federal and state regulations and corporate policies;
 - (4) financial accounting services;
 - (5) preparation of tax returns;
 - (6) audit services;
 - (7) technical support and engineering services;
 - (8) information technology support services;
 - (9) processing of accounts payable and accounts receivable;
 - (10) billing and collection services;
 - (11) payroll processing;
 - (12) security clearance services;
 - (13) compliance with import and export controls;
 - (14) procurement of insurance, including, but not limited to, general and product liability insurance; and
 - (15) legal services.
- b. The Held Separate Business shall have, at the option of the Manager with the approval of the Hold Separate Trustee, the ability to acquire services and products, including, but not limited to, those listed in Paragraph

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II.D.4.a. above, from third parties unaffiliated with Respondent.

5. Respondent shall cause the Hold Separate Trustee, the Manager, and each employee of the Held Separate Business having access to Material Confidential Information to submit to the Commission a signed statement that the individual will maintain the confidentiality required by the terms and conditions of this Hold Separate. These individuals must retain and maintain all Material Confidential Information relating to the Held Separate Business on a confidential basis and, except as is permitted by this Hold Separate, such individuals shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing, directly or indirectly, any such information to or with any other Person whose employment relates to any of Respondent's businesses other than the Held Separate Business. These individuals shall not be involved in any way in the management, research, design, development, manufacture, fabrication, assembly, marketing, distribution, sale, service, or financial operations of Respondent's In-Space Liquid Propulsion Products that compete with products or services of the Held Separate Business.
6. No later than ten (10) days after the date this Hold Separate becomes final, Respondent shall establish written procedures, subject to the approval of the Hold Separate Trustee, covering the management, maintenance, and independence of the Held Separate Business consistent with the provisions of this Hold Separate.
7. No later than five (5) days after the date this Hold Separate becomes final, Respondent shall circulate to employees of the Held Separate Business and to Respondent's employees who are responsible for the

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management, research, design, development, manufacture, fabrication, assembly, marketing, distribution, sale, service, or financial operations of In-Space Liquid Propulsion Products, a notice of this Hold Separate and Consent Agreement, in the form attached hereto as Attachment A.

8. The Hold Separate Trustee and the Manager shall serve, without bond or other security, at the cost and expense of Respondent, on reasonable and customary terms commensurate with the person's experience and responsibilities.
9. Respondent shall indemnify the Hold Separate Trustee and Manager and hold each harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Hold Separate Trustee's or the Manager's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts or omissions, or bad faith by the Hold Separate Trustee or the Manager, or their respective agents.
10. Respondent shall provide the Held Separate Business with sufficient financial resources:
 - a. as are appropriate in the judgment of the Hold Separate Trustee to operate the Held Separate Business at no less than current rates of operation and at no less than the rates of operation projected in the ARC Propulsion Division CY 03 Annual Operating Plan dated December 9, 2002 ("ARC 2003 Operating Plan");

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- b. to perform all reasonable maintenance to, and replacements of, the assets of the Held Separate Business;
- c. to carry on existing and planned capital projects and business plans for the Held Separate Business at levels no less than the levels reflected in the ARC 2003 Operating Plan;
- d. to carry on existing and planned bid and proposal and research and development plans at levels no less than the levels reflected in the ARC 2003 Operating Plan; and
- e. to maintain the viability, marketability, and competitiveness of the Held Separate Business.

Such financial resources to be provided to the Held Separate Business shall include, but shall not be limited to, (i) general funds, (ii) capital, (iii) working capital, and (iv) reimbursement for any operating losses, capital losses, or other losses; *provided, however*, that, consistent with the purposes of the Decision and Order, the Manager may substitute any capital or research and development project for another of the same cost.

11. Respondent shall:
- a. not later than forty-five (45) days before the Effective Date of Divestiture, (a) provide to the Acquirer a list of all ARC In-Space Liquid Propulsion Business Employees and ARC In-Space Liquid Propulsion Business Key Employees; (b) allow the Acquirer to interview any ARC In-Space Liquid Propulsion Business Employees; and (c) in compliance with all laws, allow the Acquirer to inspect the personnel files and other documentation relating to such ARC In-Space Liquid Propulsion Business Employees;

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- b. not later than thirty (30) days before the Effective Date of Divestiture, provide an opportunity for the Acquirer, (a) to meet personally, and outside the presence or hearing of any employee or agent of Respondent, with any one or more of the ARC In-Space Liquid Propulsion Business Employees; and (b) to make offers of employment to any one or more of the ARC In-Space Liquid Propulsion Business Employees;
- c. not directly or indirectly interfere with the Acquirer's offer of employment to any one or more of the ARC In-Space Liquid Propulsion Business Employees, not directly or indirectly attempt to persuade any one or more of the ARC In-Space Liquid Propulsion Business Employees to decline any offer of employment from the Acquirer, and not offer any incentive to any ARC In-Space Liquid Propulsion Business Employees to decline employment with the Acquirer;
- d. irrevocably waive any legal or equitable right to deter any ARC In-Space Liquid Propulsion Business Employee from accepting employment with the Acquirer, including, but not limited to, waiving any non-compete or confidentiality provisions of employment or other contracts with Respondent that relate to In-Space Liquid Propulsion Products;
- e. not interfere with the employment by the Acquirer of any ARC In-Space Liquid Propulsion Business Employee;
- f. continue employee benefits to ARC In-Space Liquid Propulsion Hold Separate Employees until the Effective Date of Divestiture consistent with the requirements of the Purchase Agreement by and between Atlantic

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Research Corporation and Aerojet-General Corporation dated May 2, 2003, and as amended August 29, 2003, including regularly scheduled or merit raises and bonuses, regularly scheduled vesting of all pension benefits, and reimbursement of relocation expenses; and

- g. provide a retention incentive bonus to ARC In-Space Liquid Propulsion Business Key Employees, who accept employment with the Commission-approved Acquirer, equal to ten (10) percent of such employee's annual salary under the following terms: (a) five (5) percent of the incentive to be paid upon the employee's completion of six (6) months of continuous employment with the Commission-approved Acquirer after the Effective Date of Divestiture; and (b) the remaining five (5) percent to be paid upon the employee's completion of one (1) year of continuous employment with the Commission-approved Acquirer after the Effective Date of Divestiture.
- 12. Subject to the provisions of Paragraph II.D.13. below, for a period of one (1) year from the Effective Date of Divestiture, Respondent shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any ARC In-Space Liquid Propulsion Business Employees who have accepted offers of employment with the Acquirer to terminate their employment relationship with the Acquirer; *provided, however*, a violation of this provision will not occur if: (1) the individual's employment has been terminated by the Acquirer, (2) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (3) Respondent hires employees who apply for employment with Respondent, as long as such employees were not solicited by Respondent in violation of this paragraph.

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13. Notwithstanding the provisions of Paragraph II.D.12. above, for a period of six (6) months from the Effective Date of Divestiture, Respondent shall not employ or make offers of employment to any ARC In-Space Liquid Propulsion Business Employees who have accepted offers of employment with the Acquirer unless any such individual's employment has been terminated by the Acquirer.
14. Except for the Manager, employees of the Held Separate Business, and support services employees involved in providing services to the Held Separate Business pursuant to Paragraph II.D.4., and except to the extent provided in Paragraph II.A., Respondent shall not permit any other of its employees, officers, or directors to be involved in the operations of the Held Separate Business.
15. Respondent's employees (excluding support services employees involved in providing support to the Held Separate Business pursuant to Paragraph II.D.4.) shall not receive, have access to, or use or continue to use any Material Confidential Information of the Held Separate Business except:
 - a. as required by law; and
 - b. to the extent that necessary information is exchanged:
 - (1) in the course of consummating the Acquisition;
 - (2) in negotiating agreements to divest assets pursuant to the Consent Agreement and engaging in related due diligence;
 - (3) in complying with the Hold Separate or the Consent Agreement;

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- (4) in overseeing compliance with policies and standards concerning the safety, health and environmental aspects of the operations of the Held Separate Business and the integrity of the financial controls of the Held Separate Business;
- (5) in defending legal claims, investigations or enforcement actions threatened or brought against or related to the Held Separate Business; or
- (6) in obtaining legal advice.

Nor shall the Manager or employees of the Held Separate Business receive, have access to, or use or continue to use, any Material Confidential Information about Respondent and relating to Respondent's businesses, except such information as is necessary to maintain and operate the Held Separate Business. Respondent may receive aggregate financial and operational information relating to the Held Separate Business only to the extent necessary to allow Respondent to prepare consolidated financial reports, tax returns, reports required by securities laws, and personnel reports. Any such information that is obtained pursuant to this paragraph shall be used only for the purposes set forth in this paragraph.

16. Respondent and the Held Separate Business shall jointly implement, and at all times during the Hold Separate Period maintain in operation, a system, as approved by the Hold Separate Trustee, of access and data controls to prevent unauthorized access to or dissemination of Material Confidential Information of the Held Separate Business, including, but not limited to, the opportunity by the Hold Separate Trustee, on terms and conditions agreed to with Respondent, to audit Respondent's networks and systems to verify compliance with this Hold Separate.

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III.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Hold Separate.

IV.

IT IS FURTHER ORDERED that for the purposes of determining or securing compliance with this Hold Separate, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent, Respondent shall permit any duly authorized representatives of the Commission:

- A. Access, during office hours of Respondent and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of the Respondent relating to compliance with this Hold Separate; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

V.

IT IS FURTHER ORDERED that this Hold Separate shall terminate at the earlier of:

- A. three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the

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provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

- B. the day after the divestiture required by the Decision and Order is completed.

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ATTACHMENT A**NOTICE OF DIVESTITURE AND REQUIREMENT FOR
CONFIDENTIALITY**

GenCorp Inc., hereinafter referred to as “Respondent,” has entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission relating to the divestiture of certain assets and other relief.

As used herein, the term “Held Separate Business” means the ARC In-Space Liquid Propulsion Business and personnel as defined in Paragraph I.L. of the Order to Hold Separate and Maintain Assets (the “Hold Separate Order”) contained in the Consent Agreement. Under the terms of the Decision and Order contained in the Consent Agreement, Respondent must divest certain assets, which are included within the Held Separate Business, within six (6) months of the date the acquisition by GenCorp of certain assets of Atlantic Research Corporation from Sequa Corporation is consummated.

During the Hold Separate Period (which begins after the Hold Separate Order becomes final and ends after Respondent has completed the required divestiture), the Held Separate Business shall be held separate, apart, and independent of Respondent’s businesses. The Held Separate Business must be managed and maintained as a separate, ongoing business, independent of all other businesses of Respondent, until Respondent has completed the required divestiture. All competitive information relating to the Held Separate Business must be retained and maintained by the persons involved in the operation of the Held Separate Business on a confidential basis, and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other of Respondent’s businesses, except as otherwise provided in the Hold Separate Order. These persons involved in the operation of the Held Separate Business shall not be involved in any way in the

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management, production, distribution, sales, marketing, or financial operations of Respondent relating to competing products. Similarly, persons involved in similar activities in Respondent's businesses shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any similar information to or with any other person whose employment involves the Held Separate Business, except as otherwise provided in the Hold Separate Order.

Until the Held Separate Business is divested, Respondent must take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Held Separate Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear.

Any violation of the Consent Agreement may subject Respondent to civil penalties and other relief as provided by law.

By the Commission.

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FEDERAL TRADE COMMISSION DECISIONS
VOLUME 136

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Confidential Appendices A and B

[Redacted from Public Record Version]

Analysis

Analysis of Agreement Containing Consent Orders to Aid Public Comment

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from GenCorp Inc. (“GenCorp”), which is designed to remedy the anticompetitive effects resulting from GenCorp’s acquisition of the propulsion business of Atlantic Research Corporation (“ARC”), a subsidiary of Sequa Corporation (“the Acquisition”). The Consent Agreement includes a proposed Decision and Order (“Order”) that would require GenCorp to divest ARC’s in-space liquid propulsion business within six (6) months after the date the Acquisition is consummated. The Consent Agreement also includes an Order to Hold Separate and Maintain Assets that requires GenCorp to preserve the ARC in-space liquid propulsion business as a viable, competitive, and ongoing operation until the divestiture is achieved.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received and will decide whether it should withdraw from the Consent Agreement or make final the Consent Agreement’s proposed Order.

On May 2, 2003, Aerojet-General Corporation (“Aerojet”), a subsidiary of GenCorp, entered into an asset purchase agreement with ARC (which was subsequently amended on August 29, 2003) to acquire substantially all of the assets of ARC, as well as the shares of ARC UK Limited, for \$133 million in cash. The Commission’s Complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade

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Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the research, development, manufacture and sale of monopropellant thrusters, bipropellant apogee thrusters, dual mode apogee thrusters, and bipropellant attitude control thrusters – four different types of in-space propulsion thrusters.

II. The Parties

GenCorp is a technology-based manufacturing company headquartered in Rancho Cordova, California. Its businesses are concentrated in three areas: aerospace and defense, fine chemicals and automotive. Through its Aerojet subsidiary, GenCorp researches, develops, manufactures and sells propulsion products and systems for space and defense applications, as well as armament systems for precision tactical weapon systems. Aerojet produces a full range of in-space propulsion thrusters at its facility located in Redmond, Washington.

Sequa Corporation (“Sequa”) is a diversified industrial company that produces a broad range of products through operating units in five business segments: aerospace, propulsion, metal coating, specialty chemicals and other products. The propulsion segment of Sequa’s business consists of the ARC business. ARC, headquartered in Gainesville, Virginia, is a leading supplier of liquid and solid fuel propulsion products and systems for military, commercial and civil applications. ARC produces a full range of in-space propulsion thrusters at its liquid propulsion facilities in Niagara, New York, and Westcott in the United Kingdom.

III. The In-Space Propulsion Markets

In-space propulsion thrusters (which are, essentially, engines) are used to maneuver spacecraft, such as satellites and interplanetary vehicles, through space after a launch vehicle delivers them to the upper atmosphere. In-space propulsion thrusters are essential components of in-space propulsion systems,

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which include valves, fuel tanks, fuel lines and other parts necessary to generate the thrust needed to move spacecraft in space.

In-space propulsion thrusters are used primarily to either place spacecraft into their intended orbits, or maintain their proper position while in orbit. The process of transferring a spacecraft to its intended orbit after it has been dropped off by a launch vehicle is referred to as “apogee insertion,” and the space propulsion thrusters that perform apogee insertion are known as “apogee thrusters.” Apogee thrusters typically generate between 90 pounds and 140 pounds of force.

Attitude control thrusters are used to provide gentle pushes that allow spacecraft to control their angular position while in orbit so that sensors, transponders or other hardware on the spacecraft are properly oriented with respect to the Earth (or other target) to perform their functions. Attitude control thrusters can also perform a function called “station-keeping,” which refers to a spacecraft’s ability to maintain its position in an assigned orbital slot, in its proper orientation. Because attitude control and station-keeping functions require only small, short bursts of thrust to perform, attitude control thrusters typically produce five pounds of thrust or less.

There are two primary types of in-space propulsion thrusters: monopropellant thrusters and bipropellant thrusters. The primary difference between these two types of thrusters is that monopropellant thrusters utilize a single liquid fuel source (typically hydrazine), whereas bipropellant thrusters operate using a combination of both a liquid fuel (typically monomethylhydrazine) and an oxidizer. Monopropellant thrusters are well-suited for pulsed operations of short duration, making them ideal for attitude control and station-keeping. As such, monopropellant thrusters typically produce less than a pound to about 5 pounds of thrust (although for particular applications, some monopropellant thrusters are designed to produce as much as 140 pounds of thrust).

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A bipropellant in-space propulsion system typically consists of separate attitude control and apogee thrusters. As with other apogee thrusters, bipropellant apogee thrusters generally produce thrust that ranges between 90 to 140 pounds of force. Bipropellant attitude control thrusters provide thrusts comparable to monopropellant thrusters, which are usually 5 pounds of force or less. Bipropellant in-space propulsion systems are more fuel efficient, as well as more expensive, than monopropellant propulsion systems.

Dual mode apogee thrusters are specialized bipropellant apogee thrusters that operate using hydrazine, the same fuel used by monopropellant thrusters, in combination with an oxidizer. A dual mode propulsion system affords spacecraft manufacturers the option of using monopropellant thrusters and a bipropellant apogee thruster on a single spacecraft without having to use two separate fuel systems. As a result, a spacecraft can attain the benefit of using highly reliable and accurate monopropellant thrusters for attitude control while at the same time utilizing bipropellant apogee thrusters. Dual mode apogee thrusters are more fuel efficient, as well as more expensive, than traditional bipropellant apogee thrusters.

The determination by customers of the appropriate type of propulsion thruster to put on a satellite or spacecraft is based on the satellite's or spacecraft's mission and encompasses a variety of factors. Those factors can include the nature of the mission, the length of the mission, the orbit(s) in which the spacecraft will operate, the mass and volume of the spacecraft itself, the launch vehicle it will be placed on, other equipment that will be on the spacecraft, and the price of the thrusters. An engineering decision is made, based on all of these factors, as to which type of propulsion thruster(s) is best suited for a particular satellite or spacecraft. Although the price of an in-space propulsion thruster is a factor that customers take into consideration when selecting an in-space propulsion thruster, it is rarely the most important factor. For these reasons, customers for one type of in-space propulsion thruster – monopropellant, bipropellant apogee, dual

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mode apogee, or bipropellant attitude control – would not be likely to switch to any of the other types of thrusters for use on a particular satellite or spacecraft, if the price of the first type of thruster were to increase by five to ten percent.

The relevant geographic market for each in-space propulsion market is the United States. Although there are a handful of foreign suppliers of in-space propulsion thrusters, they are not effective competitors in the U.S. in-space propulsion markets. The principal reason for this is that U.S. export regulations, in particular the International Traffic in Arms Regulations, make it very burdensome and time consuming for U.S. commercial, civil and defense customers to procure foreign thrusters, making foreign suppliers an unattractive option. In addition, on many U.S. Department of Defense as well as other U.S. governmental spacecraft programs, foreign-supplied thrusters are not an option at all due to national security issues. Accordingly, for the vast majority of in-space propulsion applications, only U.S. manufacturers are effective competitors.

The U.S. markets for the research, development, manufacture and sale of monopropellant, bipropellant apogee, and dual mode apogee thrusters are all highly concentrated. Aerojet and ARC are the only viable suppliers of these thrusters to commercial, civil and defense customers in the United States for most programs. Even for customers where other suppliers (such as foreign manufacturers) are potential options, Aerojet and ARC are each other's closest competitors and the other suppliers are substantially less attractive options. Prior to the acquisition, Aerojet and ARC frequently competed against each other for U.S. monopropellant, bipropellant apogee, and dual mode apogee thruster business, and this competition benefitted customers of these products. By eliminating competition between the only two viable competitors for most customers and by far the two best options for other customers in these highly concentrated markets, the proposed acquisition would create a virtual monopoly in each of these markets. As a result, the combined firm would be able to exercise market power unilaterally. It is thus likely that as a result

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of the acquisition purchasers of monopropellant, bipropellant apogee and dual mode apogee thrusters would be forced to pay higher prices and that innovation, service levels, and product quality in these markets would decrease.

The U.S. market for the research, development, manufacture and sale of bipropellant attitude control thrusters is also highly concentrated. In fact, ARC is the only firm with recent sales of bipropellant attitude control thrusters to U.S. customers. For many customers, including the vast majority of U.S. governmental customers, ARC essentially has a monopoly position in the bipropellant attitude control thruster market. Although Aerojet does not currently produce bipropellant attitude control thrusters, it has substantial existing expertise and technology in this area, has produced these thrusters in the recent past, and is a likely potential entrant into the market. Aerojet's acquisition of the ARC in-space liquid propulsion business eliminates the most likely potential competitor in this market and for many customers, including the vast majority of U.S. governmental customers, leaves the market with a single supplier for the foreseeable future.

There are significant impediments to new entry into each in-space propulsion market. A new entrant into any one of these markets would need to undertake the difficult, expensive and time-consuming process of researching and developing a viable in-space propulsion thruster, acquiring the necessary production and testing assets, obtaining the appropriate environmental permits, and developing the expertise needed to successfully design, manufacture, and market these products. Finally, a new entrant would need to establish what is commonly referred to as "heritage" for each new thruster, which is a successful track record of use in space. It would take a new entrant over two years to accomplish these steps and achieve a significant market impact. Additionally, new entry into the in-space propulsion market is unlikely to occur because the sunk costs and economies of scale necessary to enter the market and effectively produce in-space propulsion thrusters are extremely high relative to the limited sales opportunities available to new entrants.

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IV. The Consent Agreement

The Consent Agreement effectively remedies the acquisition's anticompetitive effects by requiring GenCorp to divest ARC's in-space liquid propulsion business. This business consists of, among other things, ARC's Niagara and Westcott production facilities, specialized manufacturing and testing equipment, technical drawings, advertising and training materials, customer lists, intellectual property and other assets at the Niagara and Westcott facilities used in the research, development, manufacturing, testing, marketing, customer support and sale of monopropellant, bipropellant apogee, dual mode apogee, and bipropellant attitude control thrusters (collectively "ARC In-Space Liquid Propulsion Assets"). Pursuant to the Consent Agreement, GenCorp is required to divest the ARC In-Space Liquid Propulsion Assets to a buyer, at no minimum price, within six (6) months from the date of the Acquisition. The acquirer of the ARC In-Space Liquid Propulsion Assets must receive the prior approval of the Commission.

If GenCorp has not divested the ARC In-Space Liquid Propulsion Assets within the time and in the manner required by the Consent Agreement, the Commission may appoint a trustee to divest these assets, subject to Commission approval. The trustee will have the exclusive power and authority to accomplish the divestiture within six (6) months, subject to any necessary extensions by the Commission. The Consent Agreement requires GenCorp to provide the trustee with access to information related to the ARC in-space liquid propulsion business as necessary to fulfill his or her obligations.

The proposed Order to Hold Separate and Maintain Assets that is also included in the Consent Agreement requires that GenCorp hold separate and maintain the viability of the ARC In-Space Liquid Propulsion Assets as a viable and competitive operation until the business is transferred to the Commission-approved acquirer. Furthermore, it contains measures designed to ensure that no material confidential information is exchanged between

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GenCorp and the ARC in-space liquid propulsion business (except as otherwise provided in the Order or in the Order to Hold Separate and Maintain Assets) and provisions designed to prevent interim harm to competition in each in-space propulsion market pending divestiture. The Order to Hold Separate and Maintain Assets provides for the Commission to appoint a Hold Separate Trustee who is charged with the duty of monitoring GenCorp's compliance with the Order to Hold Separate and Maintain Assets. Pursuant to that Order, the Commission has appointed Charles L. Wilkins of KPMG LLP as Hold Separate Trustee to oversee the In-Space Liquid Propulsion Assets prior to their divestiture and to ensure that GenCorp complies with its obligations under the Consent Agreement regarding the In-Space Liquid Propulsion Assets. Mr. Wilkins has more than 35 years of experience both inside the aerospace and defense industry and as a professional advisor. He has held several key management positions in the aerospace and defense industry, including senior corporate auditor, controller and chief financial officer, and during his professional consulting career has assisted most of the larger defense contractors in the United States in a wide array of services including litigation and dispute resolution, compliance matters and profit maximization.

The proposed Order requires GenCorp to provide the Commission, within thirty (30) days from the date the Order becomes final, a verified written report setting forth in detail the manner and form in which GenCorp intends to comply, is complying, and has complied with the provisions relating to the proposed Order and the Order to Hold Separate and Maintain Assets. The proposed Order further requires GenCorp to provide the Commission with a report of compliance with the Order every thirty (30) days after the date of that initial compliance report until the divestiture has been completed.

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The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement, the proposed Decision and Order, or the Order to Hold Separate and Maintain Assets, or to modify their terms in any way.