IN THE MATTER OF

FREEMAN HOSPITAL, ET AL.

Docket 9273. Interlocutory Order, Nov. 30, 1995

ORDER DISMISSING COMPLAINT

On November 6, 1995, the respondents moved that this matter be withdrawn from adjudication. Complaint counsel did not oppose the motion. On November 8, 1995, the matter was withdrawn from adjudication pursuant to Section 3.26(c) of the Commission's Rules, 16 CFR 3.26(c), for the purpose of considering whether the public interest warrants further litigation.

The "Statement of Federal Trade Commission Policy Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction," issued June 21, 1995, provides that on a case-by-case basis, the Commission will evaluate whether to pursue administrative litigation after denial of a preliminary injunction. The statement indicates that the Commission will consider the following factors in deciding whether to continue administrative litigation:

(i) The factual findings and legal conclusions of the district court or any appellate court, (ii) any new evidence developed during the course of the preliminary injunction proceeding, (iii) whether the transaction raises important issues of fact, law, or merger policy that need resolution in administrative litigation, (iv) an overall assessment of the costs and benefits of further proceeding, and (v) any other matter that bears on whether it would be in the public interest to proceed with the merger challenged.

After consideration of these factors, the Commission concludes that further litigation is not in the public interest.

It is therefore ordered, That the complaint be, and it hereby is, dismissed.

IN THE MATTER OF

AMERICAN STORES COMPANY, ET AL.

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3238. Consent Order, Aug. 31, 1988--Modifying Order, Dec. 1, 1995

This order reopens a 1988 consent order that required American Stores to divest certain retail grocery stores in parts of California and Nevada and to obtain Commission approval before acquiring certain grocery stores. This order modifies the consent order by deleting the prior-approval requirements in paragraph VIII of the consent order pursuant to the Commission's Prior Approval Policy -- under which the Commission presumes that the public interest requires reopening and setting aside the prior-approval provisions in outstanding merger orders, making them consistent with the policy -- and by replacing that provision with a prior notification provision.

ORDER REOPENING AND MODIFYING ORDER

On November 20, 1995, American Stores Company ("ASC") filed its Petition To Reopen and Vacate or Modify Consent Order ("November Petition") in this matter. Respondent asks that the Commission reopen this 1988 consent order[1] pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), Section 2.51 of the Commission's Rules of Practice and Procedure, 16 CFR 2.51, and the Statement of Federal Trade Commission Policy Concerning Prior Approval and Prior Notice Provisions, issued on June 21, 1995 ("Prior Approval Policy Statement").[2] The Petition requests that the Commission reopen and vacate the order in Docket No. C-3238, or in the alternative, reopen and modify the order by deleting the prior approval provisions of paragraph VIII.

The November Petition is identical to the Petition to reopen previously filed by ASC on July 28, 1995 ("July Petition"). Since the July Petition was subject to a thirty-day public comment period, which expired on September 8, 1995, and no comments were received, the Commission waived the public comment period for the November Petition.

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[1] *American Stores Company, et al.*, 111 FTC 80 (1988) ("American Stores").

[2] 60 Fed. Reg. 39,745-47 (Aug. 3, 1995); 4 Trade Reg. Rep. (CCH), ¶ 13,241, at 20,991 (June 21, 1995).

The Commission, in its Prior Approval Policy Statement, "concluded that a general policy of requiring prior approval is no longer needed," citing the availability of the premerger notification and waiting period requirements of Section 7A of the Clayton Act, commonly referred to as the Hart-Scott-Rodino ("HSR") Act, 15 U.S.C. 18a, to protect the public interest in effective merger law enforcement. Prior Approval Policy Statement, at 2. The Commission announced that it will "henceforth rely on the HSR process as its principal means of learning about and reviewing mergers by companies as to which the Commission had previously found a reason to believe that the companies had engaged or attempted to engage in an illegal merger." As a general matter, "Commission orders in such cases will not include prior approval or prior notification requirements." *Id.*

Narrow prior approval or prior notification provisions may be necessary to protect the public interest in some circumstances. The Commission said in its Prior Approval Policy Statement that "a narrow prior approval provision may be used where there is a credible risk that a company that engaged or attempted to engage in an anticompetitive merger would, but for the provision, attempt the same or approximately the same merger." The Commission also said that "a narrow prior notification provision may be used where there is a credible risk that a company that engaged or attempted to engage in an anticompetitive merger would, but for an order, engage in an otherwise unreportable anticompetitive merger." *Id.* at 3.

The Commission in its Prior Approval Policy Statement announced its intention "to initiate a process for reviewing the retention or modification of these existing requirements" and invited respondents subject to such requirements "to submit a request to reopen the order." *Id.* at 4. The Commission determined that, "when a petition is filed to reopen and modify an order pursuant to . . . [the Prior Approval Policy Statement], the Commission will apply a rebuttable presumption that the public interest requires reopening of the order and modification of the prior approval requirement consistent with the policy announced" in the Statement. *Id.*

Consistent with the Commission's Prior Approval Policy Statement, the presumption is that the prior approval requirement in paragraph VIII of this order should be reopened. There is nothing in the record to suggest that the respondent would engage in the same acquisition as alleged in the complaint. Accordingly, the

Commission has determined to modify the order in Docket No. C-3238 to set aside the prior approval requirement.

The Commission also stated in the Prior Approval Policy Statement that it would continue to fashion remedies as needed in the public interest, including ordering narrow prior notification requirements in certain limited circumstances. Accordingly, a prior notification provision may be used where there is a credible risk that a company would, but for an order, engage in an anticompetitive merger that would not be subject to the premerger notification and waiting period requirements of the HSR Act. As explained in the Prior Approval Policy Statement, the need for a prior notification requirement will depend on circumstances such as the structural characteristics of the relevant markets, the size and other characteristics of the market participants, and other relevant factors.

The Commission has determined that the record in this case evidences a credible risk that the respondent could engage in future anticompetitive acquisitions that would not be reportable under the HSR Act. The complaint in Docket No. C-3238 charged that respondent's proposed acquisition of Lucky would, if consummated, violate Section 7 of the Clayton Act and Section 5 of the FTC Act by substantially reducing competition in the retail sale and distribution of food and grocery store items in supermarkets in thirteen separate relevant geographic markets consisting of states, cities, areas and towns. Complaint, ¶¶ 8 and 9. Paragraph VIII of the order required respondent to obtain prior Commission approval before certain acquisitions of a retail grocery store or any interest in a retail grocery store in forty towns or areas in California and Nevada.

There has been no showing that the competitive conditions that gave rise to the Commission's complaint and order in Docket No. C-3238 no longer exist. Moreover, the size and localized nature of the relevant markets and the likely size and other characteristics of the market participants and relevant transactions as identified in the complaint and order indicate that future acquisitions that would currently be covered by the provisions of paragraph VIII of the order would probably not be subject to the premerger notification and waiting period requirements of the HSR Act.[3] Accordingly, pursuant to the Prior Approval Policy Statement, the Commission has determined to modify paragraph VIII of the order to substitute a prior

[3] *See* Order Reopening and Modifying Order, Supermarket Development Corporation, Docket No.C-3224 (Septemper 5, 1995) (Commission substituted a prior notification provision in an order based on similar complaint allegations).

notification requirement for the prior approval requirement. ASC does not object to the substitution of prior notification for prior approval. *See* Letter of Christopher J. MacAvoy to Donald C. Clark, November 20, 1995.

Accordingly, *It is ordered*, That this matter be, and it hereby is, reopened; and

It is further ordered, That paragraph VIII of the order in Docket No. C-3238, issued on August 11, 1988, be, and hereby is, modified, as of the effective date of this order, to read as follows:

It is further ordered, That, for a period of ten (10) years from the date this order becomes final, American shall cease and desist from acquiring, without prior notification to the Commission, directly or indirectly, through subsidiaries or otherwise, (i) five or more retail grocery stores, within any one year period from the date this order becomes final, including any facilities that have been operated as a retail grocery store(s) within six months of the date of the offer to purchase the facilities, or any interest in five or more retail grocery stores or any interest in any individual, firm, partnership, corporation or other legal or business entity that directly or indirectly owns or operates five or more retail grocery stores, in Los Angeles and Orange Counties, California (excluding those cities and towns identified in subsection (iii) of this Part VIII), or (ii) two or more retail grocery stores, within any one year period from the date this order becomes final, including any facilities that have been operated as a retail grocery store(s) within six months of the date of the offer to purchase the facilities, or any interest in any individual, firm, partnership, corporation or other legal or business entity that directly or indirectly owns or operates two or more retail grocery stores, in the Bay Area comprised of the following cities or towns:

Alameda, California
Albany, California
Belmont, California
Benicia, California
Berkeley, California
Burlingame, California
Campbell, California
Castro Valley, California
Cupertino, California
Newark, California
Oakland, California
Pacifica, California
Palo Alto, California
Pinole, California
Redwood City, California
Richmond, California
San Bruno, California
San Carlos, California

Daly City, California
El Cerrito, California
El Sobrante, California
Emeryville, California
Foster City, California
Fremont, California
Hayward, California
Hercules, California
Los Altos, California
Los Gatos, California
Menlo Park, California
Millbras, California
Milpitas, California
Mountain View, California
San Francisco, California
San Jose, California
San Leandro, California
San Lorenzo, California
San Mateo, California
San Pablo, California
Santa Clara, California
Saratoga, California
South San Francisco, California
Sunnyvale, California
Union City, California
Vallejo, California

or (iii) any retail grocery store, including any facility that has been operated as a retail grocery store within six months of the date of the offer to purchase the facility, or any interest in a retail grocery store or any interest in any individual, firm, partnership, corporation or other legal or business entity that directly or indirectly owns or operates a retail grocery store, in the following cities or towns:

Bakersfield, California
Camarillo, California
Canyon Country, Newhall, Saugus or Valencia, California
Capitola, California
Catheral City, Coachella, Indio, Palm Desert, Palm Springs or Rancho Mirage, California
Concord, California
Danville, California
Encinitas, California
Escondido, California
Fallbrook, California
Fontana, California
Las Vegas, Nevada
Napa, California
Novato, California
Ontario, California
Riverside, California
Salinas, California
San Bernardino, California
San Diego County, California South of the Miramar Naval Air Station, San Juan Capistrano or San Clemente, California
San Marcos, California
San Rafael, Mill Valley, Fairfax, Greenbrae, Larkspur, San Anselmo, or Sausilito, Tiburon, California
San Ramon, California
Santa Barbara, Montecito or Goleta, California
Santa Maria, California
Santa Rosa, California

Oxnard, California	Simi Valley, California
Palmdale or Lancaster, California	Thousand Oaks, California
Petaluma, California	Upland, California
Pleasanton, California	Vacaville, California
Redlands, California	Vista, California
Rialto, California	Walnut Creek, California

The prior notification required by this paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code 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 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 American and not of any other party to the transaction. American shall provide the Notification to the Commission at least thirty 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, American shall not consummate the transaction until twenty days after substantially complying with such request for additional information. 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.

Provided further that these prohibitions shall not relate to the construction of new facilities by American or the leasing by American of facilities not presently operated as a retail grocery store in those locations.

One year from the date this order becomes final and annually thereafter for nine (9) more years, American shall file with the Commission a verified written report of its compliance with this paragraph. Such reports shall include a listing of all acquisitions made by American without prior notification to the Commission in any area listed in this Part VIII.

IN THE MATTER OF

HOECHST AG

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

Docket C-3629. Complaint, Dec. 5, 1995--Decision, Dec. 5, 1995

This consent order settles alleged violations of federal law prohibiting unfair or deceptive acts and practices and unfair methods of competition arising from the $7.1 billion merger of Hoechst AG and Marion Merrell Dow Inc. The consent order, among other things, requires Hoechst -- a pharmaceutical firm -- to provide Biovail Corporation International with a letter of access to the toxicology data necessary to secure additional FDA approvals for a hypertension and cardiac drug called Tiazac (diltiazem). It also requires Hoechst to return any confidential information obtained from Biovail; to refrain from using the information; to dismiss a patent infringement lawsuit filed by Marion Merrell Dow regarding Tiazac; to withdraw a citizen petition Marion Merrell Dow filed with the Food and Drug Administration relating to Tiazac; and to agree not to file any subsequent litigation against Biovail regarding diltiazem. In addition, the consent order requires Hoechst to divest the rights to either Trental or Beraprost (two drugs intended to treat intermittent claudication, a painful leg cramping condition); to divest the rights to Pentasa (or the generic formulation), which is one of two oral forms of mesalamine used to treat ulcerative colitis and Crohn's Disease; and to divest the rights to Rifadin (or the generic formulation), which is used to treat tuberculosis. The required divestitures have to he made to Commission-approved entities, within nine months of the date of the order.

Appearances

For the Commission: *Laura A. Wilkinson, Elizabeth A. Jex, David L. Inglefield* and *Pamela L. Taylor.*

For the respondent: *William C. Pelster, Skadden, Arps, Slate, Meagher & Flom* and *Bruce H. Kublik, Covington & Burling,* Washington, D.C.

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondent Hoechst AG ("Hoechst"), a German corporation subject to the jurisdiction of the Commission, has acquired all of the voting securities of Marion Merrell Dow Inc.

("MMD"), a Delaware corporation subject to the jurisdiction of the Commission, 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, ("FTC Act"), 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 Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its principal executive offices located in Frankfurt am Main, Germany. Respondent Hoechst operates in the United States through its wholly-owned subsidiaries, Hoechst Corporation and Hoechst-Roussel Pharmaceuticals, Inc., with their principal executive offices located at Route 202-206, Somerville, New Jersey. Respondent Hoechst is the majority owner of Copley Pharmaceuticals, Inc., a corporation, with its principal executive offices located in Canton, Massachusetts.

2. MMD is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its principal place of business located at 9300 Ward Parkway, Kansas City, Missouri.

II. JURISDICTION

3. Respondent Hoechst 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 affects commerce as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. 44.

III. THE MERGER

4. Respondent Hoechst has acquired all of the voting securities of MMD for consideration valued at approximately $7.1 billion ("Merger"). The combined entity is doing business in the United States as Hoechst Marion Roussel, Inc.

IV. THE RELEVANT MARKETS

5. The relevant lines of commerce in which to analyze the effects of the Merger are the research, development, manufacture and sale of:

(1) Once-a-day diltiazem, which is used to treat hypertension (high blood pressure) and angina (severe chest pains);

(2) Oral dosage forms of mesalamine, which is used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease;

(3) Rifampin, which is used to treat tuberculosis (TB); and

(4) Drugs approved by the Food and Drug Administration ("FDA") for the treatment of intermittent claudication, a severe cramping in the legs caused by inadequate blood flow to the affected muscles due to arteriosclerosis.

6. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger.

V. STRUCTURE OF THE MARKETS

7. The once-a-day diltiazem market is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Cardizem CD® has a dominant share of the once-a-day diltiazem market. Sales of once-a-day diltiazem products in the U.S. amounted to approximately $1 billion in 1994. Prior to the Merger, Hoechst and Biovail International Corporation ("Biovail") were jointly developing a new once-a-day diltiazem product, Tiazac®, that would have competed against MMD's Cardizem CD®.

8. Hoechst devised a plan to "fix-it-first" whereby it returned to Biovail its rights to Tiazac® prior to the Merger. The purported fix fails to remedy the anticompetitive effects of the Merger, because it leaves Biovail as a less effective competitor than it would have been absent the Merger.

9. The market for oral dosage forms of mesalamine is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Pentasa® has a significant share of the market for oral dosage forms of mesalamine. There is only one other oral dosage form of mesalamine approved by the FDA. Sales of mesalamine amounted to approximately $70 million in 1994. Prior to the Merger, Hoechst

begun research and development of a generic oral dosage form of mesalamine that would have competed against MMD's Pentasa®.

10. The rifampin market is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Rifadin® has a dominant share of the rifampin market. Sales of rifampin amounted to approximately $18 million in 1994. Prior to the Merger, Hoechst was one of only a few companies that had begun research and development of a generic rifampin product that would have competed against MMD's Rifadin®.

11. The market for drugs to treat intermittent claudication is highly concentrated as measured by the Herfindahl-Hirschmann Index. Hoechst's Trental® is the only drug approved by the FDA for the treatment of intermittent claudication, and Hoechst is developing improved formulations of Trental®. In 1994, Trental®'s sales were approximately $180 million. MMD is one of only a few companies engaged in advanced stages of research and development of drugs for use in the treatment of intermittent claudication that would have competed against Hoechst's Trental® franchise.

VI. BARRIERS TO ENTRY

12. Entry into the relevant markets is difficult and time consuming. FDA regulations create long lead times for the introduction of new drugs. Additionally, patents create large and often insurmountable barriers to entry.

VII. EFFECTS OF THE MERGER

13. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the once-a-day diltiazem market 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 1993, Hoechst and MMD began the negotiations that ultimately resulted in the Merger. At the same time, Hoechst and Biovail were developing Tiazac®, a once-a-day diltiazem product. The pendency of the merger negotiations affected Hoechst's incentives with respect to the development of Tiazac®.

14. Just before finalizing the Merger, Hoechst returned its rights to Tiazac® to Biovail. The purported "fix-it-first" failed to remedy the anticompetitive effects of the Merger, because it leaves Tiazac®

as a less effective competitive product than it would have been absent the Merger.

15. The Merger eliminates actual and perceived potential competition between MMD's Cardizem® CD and Tiazac®. Effective competition between Tiazac® and Cardizem® CD will benefit consumers by leading to lower prices for once-a-day diltiazem.

16. The Merger provides the leading competitor in the once-a-day diltiazem market with access to competitively sensitive non-public information relating to Tiazac®, thereby: (1) reducing innovation in the market for once-a-day diltiazem; and (2) increasing prices in the market for once-a-day diltiazem.

17. The Merger also enhances the likelihood of collusion or interdependent coordination between or among the firms in the market for once-a-day diltiazem.

18. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for oral dosage forms of mesalamine 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. The Merger (1) eliminates actual potential competition in the market for oral dosage forms of mesalamine and (2) enhances the likelihood of collusion or interdependent coordination between or among the firms in the market for oral dosage forms of mesalamine.

19. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for rifampin 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. The Merger eliminates actual potential competition in the market for rifampin.

20. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for drugs for the treatment of intermittent claudication 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. The Merger eliminates actual potential competition in the market for drugs for the treatment of intermittent claudication.

VIII. VIOLATIONS CHARGED

21. The Merger described in paragraph four constitutes 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.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the merger of Hoechst AG ("Hoechst"), through its United States subsidiary, Hoechst Corporation, and Marion Merrell Dow Inc. ("MMD"), and Hoechst, hereinafter sometimes referred to as "respondent," having been furnished thereafter with a copy of a draft of the 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 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 a consent order, an admission by 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, 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 accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons 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 Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of Germany, with its principal place of business located at 65926 Frankfurt am Main, Germany.

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"* or *"Hoechst"* means Hoechst AG, its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Hoechst AG; subsidiaries, divisions, groups and affiliates in which Hoechst AG owns more than 25 percent of the voting securities; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

B. *"MMD"* means Marion Merrell Dow Inc., its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Marion Merrell Dow Inc.; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

C. *"Merger"* means the merger of Hoechst and MMD through the acquisition by Hoechst of the voting securities of MMD pursuant to a Stock Purchase Agreement and an Agreement and Plan of Merger both dated as of May 3, 1995.

D. *"Commission"* means the United States Federal Trade Commission.

E. *"FDA"* means the United States Food and Drug Administration.

F. *"NDA"* means new drug application.

G. *"ANDA"* means abbreviated new drug application.

H. *"Diltiazem"* means any formulation of the compound diltiazem hydrochloride used in the treatment of hypertension or angina.

I. *"Biovail"* means Biovail Corporation International, organized and existing under the laws of Canada and with its offices and principal place of business at 460 Comstock Road, Scarborough, Ontario, Canada, including its successors, licensees and assigns.

J. *"Biovail diltiazem products"* means the sustained release and\or extended release diltiazem products that Hoechst was developing with Biovail pursuant to the Rights Agreement that Hoechst and Biovail entered into on June 30, 1993.

K. *"Documents"* means all computer files and written, recorded, and graphic materials of every kind. The term "documents" includes electronic correspondence and drafts of documents, originals and all copies of documents, and copies of documents the originals of which are not in the possession, custody or control of the company.

L. *"Non-public information"* means any information or documents not in the public domain furnished by Biovail to Hoechst in connection with the Biovail diltiazem products. Non-public information shall not include information that subsequently becomes public or falls within the public domain through no violation of this order by respondent or nor shall it include information that subsequently becomes known to respondent from a third-party not in breach of a confidential disclosure agreement.

M. *"Beraprost"* means the prostaglandin analog(s) licensed by Toray Industries, Inc. to MMD used for the treatment of peripheral arterial disease, including, but not limited to, intermittent claudication.

N. *"Beraprost assets"* means all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of Beraprost, that are not part of MMD's physical facilities. "Beraprost assets" include, but are not limited to, all rights to brand or trade name, formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, information stored on management information systems (and specifications sufficient for the acquirer to use such information), software specific to MMD's Beraprost, inventory sufficient for the acquirer to complete all safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals, and all data, contractual rights, materials and information relating to

obtaining FDA approvals and other government or regulatory approvals for the United States.

O. *"Trental®"* means the compound pentoxifylline marketed by Hoechst for use in the treatment of vascular disease, including, but not limited to, intermittent claudication.

P. *"Trental® assets"* means all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of Trental®, including the unique physical assets used by Hoechst to manufacture Trental® and all of its brand names and trade names. "Trental® assets" include, but are not limited to, all rights to brand or trade name, formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, information stored on management information systems (and specifications sufficient for the acquirer to use such information), software specific to Hoechst's Trental®, and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

Q. *"Mesalamine"* means the compound mesalamine used for the treatment of ulcerative colitis and Crohn's disease.

R. *"Mesalamine assets"* means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by MMD, including the unique physical assets used MMD to manufacture mesalamine and all of its brand names and trade names. "Mesalamine assets" include, but are not limited to, all rights to brand or trade names, all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, information stored on management information systems (and specifications sufficient for the acquirer to use such information), inventory sufficient for the acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual

rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

S. *"Rifampin"* means the compound rifampin used for the treatment of tuberculosis.

T. *"Rifampin assets"* means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) MMD's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by MMD, including the unique physical assets used by MMD to manufacture rifampin and all of its brand names and trade names. "Rifampin assets" include, but are not limited to, all rights to brand or trade names, all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, information stored on management information systems (and specifications sufficient for the acquirer to use such information), inventory sufficient for the acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

U. *"Acquirer"* means the entity or entities to whom Hoechst shall divest the assets required to be divested pursuant to this order.

V. *"Contract manufacture"* means the manufacture of Trental®, mesalamine or rifampin, as applicable, by Hoechst for sale to an acquirer in a form acceptable for commercial sale in the United States, in each form of packaging used by respondent or MMD in the distribution and sale of such product, with information including, but not limited to, the name and identification codes of the acquirer inscribed on the packaging, and packaged in units specified by the acquirer, as permitted by the FDA.

W. *"Cost"* means respondent's or MMD's actual per unit cost of manufacturing the assets to be divested pursuant to this order.

X. *"Formulation"* means any and all information, including patent, trade secret information, technical assistance and advice, relating to the manufacture of the assets to be divested pursuant to this order that meet FDA approved specifications therefor.