

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2016, TO JUNE 30, 2016

PUBLISHED BY THE COMMISSION

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**MEMBERS OF THE FEDERAL TRADE COMMISSION
DURING THE PERIOD
JANUARY 1, 2016 TO JUNE 30, 2016**

EDITH RAMIREZ, *Chairwoman*
Took oath of office April 5, 2010.

JULIE BRILL, *Commissioner*
Took oath of office April 6, 2010.

MAUREEN K. OHLHAUSEN, *Commissioner*
Took oath of office April 4, 2012.

TERRELL McSWEENY, *Commissioner*
Took oath of office April 28, 2014

DONALD S. CLARK, *Secretary*
Appointed August 28, 1988.

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FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2016, TO JUNE 30, 2016

IN THE MATTER OF

NXP SEMICONDUCTORS N.V.

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

Docket No. C-4560; File No. 151 0090
Complaint, November 25, 2015 – Decision, January 21, 2016

This consent order addresses the \$11.8 billion acquisition by NXP Semiconductors N.V. of certain assets of Freescale Semiconductor Ltd. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by substantially lessening competition in the worldwide market for RF power amplifiers. The consent order requires NXP to divest its RF power amplifier assets to Jianguang Asset Management Co., Ltd. The assets to be divested include a manufacturing facility located in Cabuyao (Philippines), a building in Nijmegen (the Netherlands) to house management and certain R&D and testing labs, all manufacturing and R&D assets used primarily for the RF power amplifier business, and customer support equipment.

Participants

For the *Commission*: *Mac Conforti* and *Meredith Levert*.

For the *Respondent*: *Peter Guryan*, *Simpson Thacher & Bartlett LLP*; and *Erik Pinjacker Hordjik*, *De Brauw, Blackstone, and Westbroek*.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent NXP Semiconductors N.V. (“NXP”), a corporation

Complaint

subject to the jurisdiction of the Commission, has agreed to acquire Freescale Semiconductor, Ltd. (“Freescale”), a 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 (“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 NXP is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its office and principal place of business located in Eindhoven, the Netherlands.

2. Freescale is a public limited liability company organized, existing, and doing business under and by virtue of the laws of Bermuda, with its office and principal place of business located at 6501 William Cannon Drive West, Austin, Texas 78735.

3. Respondent NXP is engaged in the design, manufacture, and sale of a range of semiconductor products used in a variety of electronic systems for automotive, communications, industrial, consumer, and other applications.

4. Freescale is engaged in the design, manufacture, and sale of a range of semiconductor products used in a variety of electronic systems for automotive, communications, industrial, consumer, and other applications.

5. Respondent and Freescale are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

Complaint

II. THE PROPOSED ACQUISITION

6. Pursuant to an Agreement and Plan of Merger dated March 1, 2015, Respondent and Freescale agreed that NXP would acquire Freescale for approximately \$11.8 billion (“the Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKET

7. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is RF power amplifiers. RF power amplifiers (also called RF power transistors) are high power (>1 watt average output power) semiconductors that amplify radio signals used to transmit information between electronic devices.

8. For the purposes of this Complaint, the relevant geographic market in which to analyze the effects of the Acquisition in the RF power amplifier market is worldwide. Transportation costs are low for RF power amplifiers, which are routinely shipped from manufacturing facilities around the globe to customer locations worldwide.

IV. STRUCTURE OF THE MARKET

9. The market for RF power amplifiers worldwide is highly concentrated. Freescale and NXP are the two largest manufacturers of RF power amplifiers, with a combined market share of more than 60% based on revenues. The proposed merger would increase the Herfindahl-Hirschman Index from 2,203 to 4,040, an increase of 1,837. This increase in concentration far exceeds the thresholds set out in the *Horizontal Merger Guidelines* for raising a presumption that the Acquisition would create or enhance market power.

V. ENTRY CONDITIONS

10. Given the substantial time and investment required to develop RF power amplifiers, entry sufficient to deter or

Complaint

counteract the anticompetitive effects created by the Acquisition is unlikely.

VI. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. The Acquisition would eliminate the direct competition between NXP and Freescale, which may lead to anticompetitive unilateral effects in the form of higher prices and reduced innovation.

VII. VIOLATIONS CHARGED

12. The allegations contained in Paragraphs 1 through 11 above are hereby incorporated by reference as though fully set forth here.

13. The Agreement described in Paragraph 6 constitutes a violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 6, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-fifth day of November, 2015, issues its Complaint against said Respondent.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission, having initiated an investigation of the proposed acquisition by Respondent NXP Semiconductors N.V. (“NXP”) of the outstanding voting securities of Freescale Semiconductor, Ltd. (“Freescale”) and Respondent having been furnished thereafter with a copy of 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 attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, 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, 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 accepted the 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 to Maintain Assets:

1. Respondent NXP Semiconductors N.V. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the Netherlands, with its corporate office and principal place of

Order to Maintain Assets

business located at High Tech Campus 60, Eindhoven 5656 AG, the Netherlands.

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 HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions shall apply (to the extent any capitalized term appearing in this Order to Maintain Assets is not defined below, the term shall be defined as that term is defined in the Decision and Order contained in the Consent Agreement):

- A. “NXP” means NXP Semiconductors N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates in each case controlled by NXP Semiconductors N.V. (including Freescale, after the Acquisition) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means (i) JAC or (ii) any other Person that acquires the RF Power Assets pursuant to the Decision and Order.
- D. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger by and among NXP Semiconductors N.V., Nimble Acquisition Limited, and Freescale Semiconductor, Ltd., dated March 1, 2015.

Order to Maintain Assets

- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Confidential Information” means any and all of the following information:
1. all information that is a trade secret under applicable trade secret or other law;
 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer hardware, software and computer software and database technologies, systems, structures, and architectures;
 3. all information concerning the relevant business (which includes historical and current financial statements, financial projections and budgets, tax returns and accountants’ materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications, client and customer lists and files, contracts, the names and backgrounds of key personnel and personnel training techniques and materials); and
 4. all notes, analyses, compilations, studies, summaries and other material to the extent containing or based, in whole or in part, upon any of the information described above;

Provided, however, that Confidential Information shall not include information that (i) was, is or becomes generally available to the public other than as a result

Order to Maintain Assets

of a breach of this Order; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary or other obligation restricting disclosure.

- G. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission in this matter following the issuance and service of a final Decision and Order by the Commission.
- H. “Divestiture Agreement” means (i) the JAC Acquisition Agreement or (ii) any other agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the RF Power Assets, including all related ancillary agreements (transitional services agreement, intellectual property transfer and license agreement, and manufacturing services agreement), schedules, exhibits, and attachments thereto.
- I. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the transaction to divest the RF Power Assets to Acquirer.
- J. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.

Order to Maintain Assets

- K. “RF Power Assets” means the assets identified in Paragraph I.V. of the Decision and Order.
- L. “RF Power Business” means the business conducted by NXP as of the date of the announcement of the Acquisition in respect of researching, designing, developing, testing, manufacturing, commercializing, packaging, marketing, distributing, selling and/or servicing high power RF Power transistors (from >1 watt peak power to more than 1kW) for applications including but not limited to cellular base stations, broadcast systems, radars, medical equipment and various industrial applications, which are manufactured using Silicon Lateral Diffused Metal Oxide Semiconductor (Si-LDMOS), Vertical Diffused Metal Oxide Semiconductor (VDMOS) or Gallium Nitride on Silicon Carbide (GaN-on-SiC) process technologies in order to be able to deliver the desired high output power and heat dissipation and any past and/or future generations of such transistors, technologies, or markets.
- M. “RF Power Employee” means any individual (i) employed by NPX on a full-time, part-time, or contract basis at any time as of and after the date of the announcement of the Acquisition and (ii) whose job responsibilities predominantly relate or predominantly related to the RF Power Business.

II.

IT IS FURTHER ORDERED that until the Divestiture Date, Respondent shall secure all consents, assignments, and waivers from all Persons that are necessary for the divestiture of the RF Power Assets and grant of the RF Power License; *provided, however,* that Respondent may satisfy this requirement by certifying that Acquirer has executed appropriate agreements directly with each of the relevant Persons; and *provided further* that in the event Respondent is unable to obtain any consent, assignment, or waiver required by this Paragraph II., Respondent shall (i) provide such assistance as Acquirer may reasonably

Order to Maintain Assets

request in its efforts to obtain the consent or (ii) with the acceptance of Acquirer and the prior approval of the Commission, Respondent may substitute equivalent assets or arrangements.

III.

IT IS FURTHER ORDERED that during the time period before the Divestiture Date, Respondent shall operate the RF Power Business and RF Power Assets in the ordinary course of business consistent with past practices as of the date that Respondent announced the Acquisition, including but not limited to the following responsibilities:

- A. Respondent shall maintain (i) the RF Power Business and RF Power Assets in substantially the same condition (except for normal wear and tear) existing at the time Respondent signs the Consent Agreement, and (ii) relations and good will with suppliers, customers, landlords, creditors, agents, and other having business relationships with the RF Power Business and RF Power Assets;
- B. Respondent shall provide the RF Power Business with sufficient financial and other resources to (i) operate the RF Power Business and RF Power Assets at least at the current rate of operation and staffing and to carry out, at their scheduled pace, all business plans and promotional activities in place prior to the Acquisition; (ii) perform all maintenance to, and replacements or remodeling of, the assets of the RF Power Business in the ordinary course of business and in accordance with past practice and current plans; (iii) carry on such capital projects, physical plant improvements, and business plans as are already underway or planned for which all necessary regulatory and legal approvals have been obtained, including but not limited to existing or planned renovation, remodeling, or expansion projects; and (iv) maintain the viability, competitiveness, and marketability of the RF Power Business and RF Power Assets.

Order to Maintain Assets

- C. Respondent shall preserve the RF Power Business and RF Power Assets as an ongoing business and not take any affirmative action, or fail to take any action within Respondent's control, as a result of which the viability, competitiveness, and marketability of the RF Power Business and RF Power Assets would be diminished.

IV.**IT IS FURTHER ORDERED** that:

- A. Until the Divestiture Date, Respondent shall staff the RF Power Business and RF Power Assets with sufficient employees to maintain the viability and competitiveness of the RF Power Business and RF Power Assets, including but not limited to, providing each RF Power Employee with reasonable financial incentives, if necessary, including continuation of all employee benefits and regularly scheduled raises and bonuses, to continue in his or her position pending divestiture of the RF Power Assets.
- B. Respondent shall cooperate with and assist Acquirer to evaluate and retain any RF Power Employee necessary to operate the RF Power Business in substantially the same manner as NXP prior to the divestiture, including but not limited to:
 - 1. Not later than twenty (20) days before the Divestiture Date, Respondent shall (i) identify all RF Power Employees, (ii) allow Acquirer to inspect the personnel files and other documentation of all RF Power Employees, to the extent permissible under applicable laws, and (iii) allow Acquirer an opportunity to interview any RF Power Employee;
 - 2. Respondent shall (i) not offer any incentive to any RF Power Employee to decline employment with Acquirer, (ii) remove any contractual impediments that may deter any RF Power Employee from

Order to Maintain Assets

accepting employment with Acquirer, including but not limited to, any non-compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by Acquirer, and (iii) not otherwise interfere the recruitment, hiring, or employment of any RF Power Employee by Acquirer;

3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with Acquirer for any RF Power Employee who accepts an offer of employment from Acquirer and (ii) provide each RF Power Employee with reasonable financial incentive as necessary to accept offers of employment with Acquirer; and
4. For a period of two (2) years after the RF Power Assets are divested, Respondent shall not solicit the employment of any RF Power Employee who becomes employed by Acquirer at the time the RF Power Assets are divested; *provided, however*, that a violation of this provision will not occur if: (i) the individual's employment has been terminated by Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.

V.

IT IS FURTHER ORDERED that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Information received or maintained by Respondent relating to the

Order to Maintain Assets

RF Power Business or RF Power Assets; *provided, however,* that Respondent may disclose or use such Confidential Information in the course of:

1. Performing its obligations or as permitted under this Order to Maintain Assets, Decision and Order, or Divestiture Agreement; or
 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the RF Power Business or RF Power Assets, or as required by law.
- B. If disclosure or use of any Confidential Information is permitted to Respondent's employees or to any other Person under Paragraph V.A. of this Order, Respondent shall limit such disclosure or use (i) only to the extent such information is required, (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph V.A., and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.
- C. Respondent shall enforce the terms of this Paragraph V. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph V., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

Order to Maintain Assets

VI.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint Advolis S.A. to serve as Monitor.
- B. Respondent shall enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order to Maintain Assets and in consultation with the Commission:
 - 1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order to Maintain Assets and the Decision and Order, and (ii) act in a fiduciary capacity for the benefit of the Commission;
 - 2. Respondent shall (i) insure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order to Maintain Assets and the Decision and Order, or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order to Maintain Assets;
 - 3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may employ, at the cost and expense of

Order to Maintain Assets

Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his 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 the Monitor's gross negligence or willful misconduct; and
 5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- C. The Monitor shall report in writing to the Commission (i) every thirty (30) days after the Acquisition Date for a period of one year, (ii) every ninety (90) days thereafter until Respondent has completed all obligations required by Paragraph II. of the Decision and Order, and (iii) at any other time as requested by the staff of the Commission, concerning Respondent's compliance with this Order to Maintain Assets and the Decision and Order.
- D. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

Order to Maintain Assets

- E. The Monitor's power and duties under this Order to Maintain Assets shall terminate at the time this Order to Maintain Assets terminates, or at such other time as directed by the Commission.
- F. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld:
1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after notice by the staff of the Commission to Respondent of the identity of any substitute Monitor, then Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor; and
 2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Monitor, enter into an agreement with the substitute Monitor that, subject to the approval of the Commission, confers on the substitute Monitor all the rights, powers, and authority necessary to permit the substitute Monitor to perform his or her duties and responsibilities pursuant to this Order to Maintain Assets on the same terms and conditions as provided in this Paragraph VI.
- G. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order to Maintain Assets.

Order to Maintain Assets

VII.

IT IS FURTHER ORDERED that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and Decision and Order within thirty (30) days from the date Respondent signs the Consent Agreement (as set forth in the Consent Agreement) and every thirty (30) days thereafter until this Order to Maintain Assets terminates.
- B. With respect to the divestiture required by Paragraph II. of the Decision and Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the RF Power Assets; (ii) a description of all substantive contacts with a proposed acquirer (other than JAC); and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

VIII.

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to (i) preserve the RF Power Business and RF Power Assets as a viable, competitive, and ongoing business until the divestiture required by the Decision and Order is achieved; (ii) prevent interim harm to competition pending the relevant divestiture and other relief; and (iii) help remedy any anticompetitive effects of the proposed Acquisition as alleged in the Commission's Complaint.

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

Order to Maintain Assets

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent 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 Respondent related to compliance with this Order to Maintain Assets, which copying services shall be provided by Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement

Decision and Order

pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

- B. Three (3) business days after the date that Respondent completes the divestiture required by Paragraph II.A. of the Decision and Order; *provided, however*, that if at the time such divestiture has been completed, the Decision and Order in this matter is not yet final, then this Order to Maintain Assets shall terminate three (3) business days after the Decision and Order becomes final.

By the Commission.

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The Federal Trade Commission, having initiated an investigation of the proposed acquisition by Respondent NXP Semiconductors N.V. (“NXP”) of the outstanding voting securities of Freescale Semiconductor, Ltd. (“Freescale”) and Respondent having been furnished thereafter with a copy of 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 attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, 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

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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 its 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 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 enters the following Decision and Order ("Order"):

1. Respondent NXP Semiconductors N.V. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the Netherlands, with its corporate office and principal place of business located at High Tech Campus 60, Eindhoven 5656 AG, the Netherlands.
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 HEREBY ORDERED that, as used in this Order, the following definitions shall apply:

- A. "NXP" means NXP Semiconductors N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates in each case controlled by NXP Semiconductors N.V. (including Freescale, after the Acquisition) and the respective directors, officers,

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employees, agents, representatives, successors, and assigns of each.

- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means (i) JAC or (ii) any other Person that acquires the RF Power Assets pursuant to this Order.
- D. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger by and among NXP Semiconductors N.V., Nimble Acquisition Limited, and Freescale Semiconductor, Ltd., dated March 1, 2015.
- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “BY Building” means the building located at Halfgeleiderweg 8, 6534 AV, Nijmegen, The Netherlands.
- G. “Confidential Information” means any and all of the following information:
 - 1. all information that is a trade secret under applicable trade secret or other law;
 - 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, software and computer software and database technologies, systems, structures, and architectures;
 - 3. all information concerning the relevant business (which includes historical and current financial

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statements, financial projections and budgets, tax returns and accountants' materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications, client and customer lists and files, contracts, the names and backgrounds of key personnel and personnel training techniques and materials); and

4. all notes, analyses, compilations, studies, summaries and other material to the extent containing or based, in whole or in part, upon any of the information described above;

Provided, however, that Confidential Information shall not include information that (i) was, is, or becomes generally available to the public other than as a result of a breach of this Order; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary or other obligation restricting disclosure.

- H. "Contract" means any agreement, contract, lease, license agreement, consensual obligation, promise or undertaking (whether written or oral and whether express or implied), whether or not legally binding with third parties.
- I. "Corporate Trade Names" means all NXP's commercial names, trade names, doing business as (d/b/a) names, registered and unregistered trademarks and service marks.
- J. "Cost" means the actual cost of raw materials, direct labor, and administrative expenses, and reasonably allocated operations and factory and shared corporate services overhead used to develop, manufacture, and supply the relevant good or service.

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- K. “Divestiture Agreement” means (i) the JAC Acquisition Agreement or (ii) any other agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the RF Power Assets, including all related ancillary agreements (transitional services agreement, intellectual property transfer and license agreement, and manufacturing services agreement), schedules, exhibits, and attachments thereto.
- L. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the transaction to divest the RF Power Assets to Acquirer.
- M. “Divestiture Trustee” means the Person appointed by the Commission pursuant to Paragraph V. of this Order.
- N. “Intellectual Property” means all intellectual property, including (i) commercial names, all assumed fictional business names, trade names, “doing business as” (d/b/a names), registered and unregistered trademarks, service marks and applications, and tradedress; (ii) all patents, patent applications and inventions and discoveries that may be patentable; (iii) all registered and unregistered copyrights in both published works and unpublished works; (iv) all rights in mask works; (v) all know-how, trade secrets, confidential or proprietary information, customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; (vi) and all rights in internet web sites and internet domain names presently used.
- O. “JAC” means Beijing Jianguang Asset Management Co., Ltd., a limited liability company organized, existing, and doing business under, and by virtue of, the laws of China, with its corporate office and principal place of business located at Beijing International Club Office Tower, Room 902, NO. 21, Jian Guo Men Wai Street, Beijing, China 100020.

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- P. “JAC Acquisition Agreement” means the asset purchase agreement between NXP and JAC Newco, dated October 27, 2015, including related ancillary agreements, amendments, schedules, exhibits, and attachments, thereto, that have been approved by the Commission to accomplish the requirements of this Order.
- Q. “License-Back” means a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license to Respondent from Acquirer under any Intellectual Property included in the RF Power Assets (that is not exclusively related to the operation of the RF Power Business) for use in any business operated by Respondent that does not compete with the RF Power Business.
- R. “Monitor” means the Person appointed by the Commission pursuant to Paragraph IV. of this Order.
- S. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.
- T. “Products” means (i) LDMOS and MOSCAP wafers relating to the RF Power Business and associated grinding and backside metallization and testing services, currently performed at NXP’s factory in Nijmegen, Netherlands, and NXP’s factory in Hamburg, Germany, and (ii) finished product supply services relating to the RF Power Business currently performed at NXP’s assembly plant in Kaoshiung, Taiwan, including assembly and final testing.
- U. “Qubic Intellectual Property” means all Intellectual Property related to NXP’s Qubic Bi-CMOS process technology, whether used in or for the research, development, design, or manufacture of products, and

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any patents or other Intellectual Property Rights associated therewith.

- V. “RF Power Assets” means all of Respondent’s right, title, and interest in and to all property and assets, real, personal or mixed, tangible and intangible, of every kind and description, wherever located, and any improvements or additions thereto, relating to operation of the RF Power Business, including, but not limited to:
1. all real property interests (including fee simple interests and real property leasehold interests), including all easements, and appurtenances, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held;
 2. all Tangible Personal Property, including any Tangible Personal Property removed from any location of the RF Power Business since the date of the announcement of the Acquisition, and not replaced, unless such Tangible Personal Property was removed in the ordinary course of business and has a replacement cost of less than \$5,000;
 3. all inventories, including all raw materials, finished goods, dies, semi-finished goods, work in progress, and goods in transit;
 4. all Contracts and all outstanding offers or solicitations to enter into any Contract, and all rights thereunder and related thereto;
 5. all consents, licenses, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, and all pending applications therefor or renewals thereof, to the extent assignable;

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6. all data and Records, including client and customer lists and Records, referral sources, research and development reports and Records, production reports and Records, service and warranty Records, equipment logs, operating guides and manuals, financial and accounting Records, creative materials, advertising materials, promotional materials, studies, reports, notices, orders, inquiries, correspondence and other similar documents and Records, and copies of all personnel Records (to the extent permitted by law);
7. all intangible rights and property, including Intellectual Property owned or licensed (as licensor or licensee) by Respondent, going concern value, goodwill, and telephone and telecopy listings;
8. all insurance benefits, including rights and proceeds; and
9. all rights relating to deposits and prepaid expenses, claims for refunds and rights to offset in respect thereof;

Provided, however, that the RF Power Assets need not include NXP's right, title, and interest in the (i) Retained Assets or (ii) Retained Intellectual Property.

- W. "RF Power Business" means the business conducted by NXP as of the date of the announcement of the Acquisition in respect of researching, designing, developing, testing, manufacturing, commercializing, packaging, marketing, distributing, selling and/or servicing high power RF Power transistors (from >1 watt peak power to more than 1kW) for applications including but not limited to cellular base stations, broadcast systems, radars, medical equipment and various industrial applications, which are manufactured using Silicon Lateral Diffused Metal Oxide Semiconductor (Si-LDMOS), Vertical Diffused Metal Oxide Semiconductor (VDMOS) or Gallium

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Nitride on Silicon Carbide (GaN-on-SiC) process technologies in order to be able to deliver the desired high output power and heat dissipation and any past and/or future generations of such transistors, technologies, or markets.

- X. “RF Power Employee” means any individual (i) employed by NXP on a full-time, part-time, or contract basis at any time as of and after the date of the announcement of the Acquisition and (ii) whose job responsibilities predominantly relate or predominantly related to the RF Power Business.
- Y. “RF Power License” means a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license under:
1. The Retained Intellectual Property sufficient for JAC or other Acquirer to operate the RF Power Business in substantially the same manner as NXP prior to the Acquisition, including the freedom to extend existing products and develop new products;
 2. Any Intellectual Property owned or licensed (as licensor or licensee) by NXP sufficient for JAC or other Acquirer to research, design, develop, test, manufacture, commercialize, package, market, distribute, sell and service “mmWave” RF power products (signal frequency > 10GHz) for 5G (or subsequent generation standards of) telecom infrastructure applications consisting of RF transceiver and PAs in the form of ICs and modules up to and including the antenna interface, manufactured in one of three specialty process technologies, being Si-LDMOS, GaN-on-SiC and RFCMOS, and for the avoidance of doubt, not in SiGe process technology, with respect to the existing roadmap of the RF Power Business prior to the Acquisition; and

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3. Such tangible embodiments of the licensed rights (including, but not limited to, physical and electronic copies) as may be necessary or appropriate to enable JAC or other Acquirer to use the rights;

Provided, however, that for any Retained Intellectual Property or other Intellectual Property licensed by NXP from a third-party, the RF Power License shall include only those rights licensed from such third-party.

- Z. “Record” means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- AA. “Retained Assets” means:
1. Corporate Trade Names and portions of website content, domain names, or e-mail addresses that contain Corporate Trade Names;
 2. Real property (except for the BY Building and the related land thereof and the SiPS Building);
 3. Trade accounts receivable accrued or prepaid by or owed to NXP prior to the date of completion of the Acquisition; and
 4. Tangible Personal Property relating to both the operation of the RF Power Business and any other business owned by NXP prior to the Acquisition, unless such Tangible Personal Property is primarily used by the RF Power Business.
- BB. “Retained Intellectual Property” means any owned or licensed (as licensor or licensee) Intellectual Property (not included in the Retained Assets) relating to both the operation of the RF Power Business and any other business owned by NXP prior to the Acquisition,

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unless such Intellectual Property is predominantly used by the RF Power Business.

- CC. “SiPS Building” means the building located at Philips Avenue, LISP 1, Barrio Diezmo Cabuyao City, Laguna, Philippines.
- DD. “Support Services” means administrative and technical services and training, including but not limited to, services and training relating to (i) audits, (ii) environmental health and safety, (iii) exporting, (iv) finance and accounting, (v) human resources, (vi) information technology, (vii) intellectual property, (viii) legal services, (ix) maintenance and repair of facilities, (x) manufacturing, (xi) pensions, (xii) purchasing, (xiii) quality control, (xiv) R&D support, (xv) real estate, (xvi) regulatory compliance, (xvii) sales and marketing, (xviii) supply chain management, (xix) technology transfer, and (xx) warehousing.
- EE. “Tangible Personal Property” means all machinery, equipment, tools, furniture, office equipment, computer hardware, supplies, materials, vehicles, and other items of tangible personal property (other than inventories) of every kind owned or leased, together with any express or implied warranty by the manufacturers or sellers or lessors of any item or component part thereof and all maintenance records and other documents relating thereto.
- FF. “Volcano Chip RFE001” means NXP’s Volcano chip RFE001 designed in Qubic technology as available today, without any further future amendment or updates.

II.**IT IS FURTHER ORDERED** that:

- A. No later than ten (10) days after the Acquisition Date, Respondent shall divest the RF Power Assets and grant

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the RF Power License, absolutely and in good faith, to JAC pursuant to the JAC Acquisition Agreement.

- B. If Respondent has divested the RF Power Assets to JAC prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that:
1. JAC is not acceptable as the acquirer of the RF Power Assets, then Respondent shall immediately rescind the JAC Acquisition Agreement, and shall divest the RF Power Assets and grant the RF Power License no later than 120 days from the date this Order is issued, absolutely and in good faith, at no minimum price, to a Person that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; or
 2. The manner in which the divestiture or grant of license to JAC was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications (that shall be incorporated into a revised JAC Divestiture Agreement) to the manner of divestiture of the RF Power Assets or grant of the RF Power License as the Commission may determine are necessary to satisfy the requirements of this Order.
- C. Notwithstanding any other provision of this Order, Respondent may (i) enter into an agreement with JAC or other Acquirer for a License-Back (subject to the prior approval of the Commission) or (ii) lease the SiPS Building to JAC or other Acquirer for a period not to exceed two (2) years prior to divesting the building absolutely to JAC or other Acquirer.
- D. No later than the Divestiture Date, Respondent shall secure all consents, assignments, and waivers from all Persons that are necessary for the divestiture of the RF

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Power Assets and grant of the RF Power License; *provided, however*, that Respondent may satisfy this requirement by certifying that Acquirer has executed appropriate agreements directly with each of the relevant Persons; and *provided further* that in the event Respondent is unable to obtain any consent, assignment, or waiver required by this Paragraph II.D., Respondent shall (i) provide such assistance as Acquirer may reasonably request in its efforts to obtain the consent or (ii) with the acceptance of Acquirer and the prior approval of the Commission, Respondent may substitute equivalent assets or arrangements.

E. Respondent shall:

1. At the request of Acquirer and in a manner that receives the prior approval of the Commission, provide (a) Products for a period of up to sixty (60) months and (b) Support Services for a period of up to thirty-six (36) months, from the Divestiture Date (collectively “Transitional Assistance”); and
2. Provide the Transitional Assistance required by this Order at a price not to exceed Cost and in quality and quantity sufficient to enable Acquirer to operate the RF Power Business in substantially the same manner as NXP prior to the Acquisition, including the ability to develop new products and increase sales of current products;

Provided, however, that if the quantity of Transitional Assistance pursuant to a Divestiture Agreement is limited for any reason, Respondent shall give priority to Acquirer’s requirements over its own;

Provided further that the time periods for providing Transitional Assistance shall be extended, at the request of Acquirer, subject to the prior approval of the Commission; and

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Provided further that Respondent shall not (i) terminate its obligation to provide any Transitional Assistance because of a material breach by Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction or (ii) seek to limit the damages (such as indirect, special, and consequential damages) which Acquirer would be entitled to receive in the event of Respondent's breach of any agreement to provide Transitional Assistance.

F. No later than the Divestiture Date and in a manner that receives the prior approval of the Commission, Respondent shall:

1. Divest any and all Intellectual Property (excluding the Qubic Intellectual Property) to Acquirer necessary to enable Acquirer to redesign the Volcano Chip RFE001 using a process technology other than NXP's Qubic technology, including but not limited to, datasheets, application notes, PCB design files, PCB Gerber and Drill files, PCB BOM, software, architecture diagrams, block level design documents, simulation plan and reports, change reports, and problem report lists;

Provided, however, that NXP may license to Acquirer rights in software and other design documents relating to the Volcano Chip RFE001 that NXP also uses for other purposes;

2. Provide technical assistance as requested by Acquirer at a price not to exceed Cost to enable Acquirer to redesign the Volcano Chip RFE001 using a process technology other than NXP's Qubic technology;
3. For a period of up to sixty (60) months, manufacture and deliver the Volcano Chip RFE001 exclusively for Acquirer at a price not to exceed Cost and in such quantity and quality as requested

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by Acquirer; *provided, however*, that the time period set forth in this Paragraph II.F. 3. shall be extended, at the request of Acquirer, subject to the prior approval of the Commission; and

4. Not join, file, prosecute, or maintain any suit, in law or equity, against Acquirer or any Person working on behalf of Acquirer under the Qubic Intellectual Property, if such suit would have the potential to limit or interfere with Acquirer's freedom to use the Volcano Chip RFE001 or the redesigned Volcano Chip RFE001 in any application of the RF Power Business;

Provided further that Respondent shall not (i) terminate its obligation to provide any assistance pursuant to Paragraphs II.F.2. or II.F.3. because of a material breach by Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction or (ii) seek to limit the damages (such as indirect, special, and consequential damages) which Acquirer would be entitled to receive in the event of Respondent's breach of any agreement to such assistance.

- G. Notwithstanding any provision of this Order, Respondent shall permit Acquirer to use the name "NXP Semiconductors" or "NXP," or any abbreviation thereof, or any name, logo, or lettering which is similar, in the operation of the RF Power Business for a period of up to nine (9) months from the Divestiture Date.
- H. Respondent shall cooperate with and assist Acquirer to evaluate and retain any and all RF Power Employees necessary to operate the RF Power Business in substantially the same manner as NXP prior to the divestiture, including but not limited to:
 1. Not later than twenty (20) days before the Divestiture Date, Respondent shall (i) identify all

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RF Power Employees, (ii) allow Acquirer to inspect the personnel files and other documentation of all RF Power Employees, to the extent permissible under applicable laws, and (iii) allow Acquirer an opportunity to interview any RF Power Employee;

2. Respondent shall (i) not offer any incentive to any RF Power Employee to decline employment with Acquirer, (ii) remove any contractual impediments that may deter any RF Power Employee from accepting employment with Acquirer, including but not limited to, any non-compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by Acquirer, and (iii) not otherwise interfere with the recruitment, hiring, or employment of any RF Power Employee by Acquirer;
3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with Acquirer for any RF Power Employee who accepts an offer of employment from Acquirer and (ii) provide each RF Power Employee with reasonable financial incentive as necessary to accept offers of employment with Acquirer; and
4. For a period of two (2) years after the RF Power Assets are divested, Respondent shall not solicit the employment of any RF Power Employee who becomes employed by Acquirer at the time the RF Power Assets are divested; *provided, however*, that a violation of this provision will not occur if: (i) the individual's employment has been terminated by Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so

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long as such employees were not solicited by Respondent in violation of this paragraph.

- I. The Commission may order Respondent to divest additional Tangible Personal Property relating to the RF Power Business not included in the RF Power Assets or effect other appropriate arrangements relating to such divestitures as the Commission determines are necessary to ensure the divestiture of the RF Power Assets as an ongoing viable enterprise, except for such Tangible Personal Property or other appropriate arrangements which can readily be obtained from sources other than Respondent.
- J. The purpose of the divestiture of the RF Power Assets is to ensure the continued use of the assets in the same businesses in which such assets were engaged at the time of the announcement of the Acquisition by Respondent and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Information received or maintained by Respondent relating to the RF Power Business or RF Power Assets; *provided, however,* that Respondent may disclose or use such Confidential Information in the course of:
 - 1. Performing its obligations or as permitted under this Order, the Order to Maintain Assets, or Divestiture Agreement; or
 - 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions

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threatened or brought against the RF Power Business or RF Power Assets, or as required by law.

- B. If disclosure or use of any Confidential Information is permitted to Respondent's employees or to any other Person under Paragraph III.A. of this Order, Respondent shall limit such disclosure or use (i) only to the extent such information is required, (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph III.A., and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.
- C. Respondent shall enforce the terms of this Paragraph III. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph III., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

IV.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint Advolis S.A. to serve as Monitor. The Monitor may be the same person as the Monitor appointed pursuant to the Order to Maintain Assets.
- B. Respondent shall enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to

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permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order and in consultation with the Commission:

1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
2. Respondent shall (i) insure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order;
3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may 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 Monitor's duties and responsibilities;
4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his 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 the Monitor's gross negligence or willful misconduct; and

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5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- C. The Monitor shall report in writing to the Commission (i) every thirty (30) days after the Acquisition Date for a period of one (1) year, (ii) every ninety (90) days thereafter until Respondent has completed all obligations required by Paragraph II. of this Order (including a final report when Respondent has completed all such obligations), and (iii) at any other time as requested by the staff of the Commission, concerning Respondent's compliance with this Order.
 - D. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - E. The Monitor's power and duties shall terminate ten (10) business days after the Monitor has completed his final report pursuant to Paragraph IV.C.(ii) of this Order, or at such other time as directed by the Commission.
 - F. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld:
 1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after

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notice by the staff of the Commission to Respondent of the identity of any substitute Monitor, then Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor; and

2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Monitor, enter into an agreement with the substitute Monitor that, subject to the approval of the Commission, confers on the substitute Monitor all the rights, powers, and authority necessary to permit the substitute Monitor to perform his or her duties and responsibilities pursuant to this Order on the same terms and conditions as provided in this Paragraph IV.
- G. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

V.

IT IS FURTHER ORDERED that:

- A. If Respondent has not fully complied with the divestiture and other obligations as required by Paragraph II. of this Order, the Commission may appoint a Divestiture Trustee to divest the RF Power Assets and perform Respondent's other obligations in a manner that satisfies the requirements of this Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor.
- B. In the event that the Commission or the 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

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Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture 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. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or other action required by the Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive

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power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and to take such other action as may be required to divest the Divestiture Assets.

2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the 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 Divestiture Trustee, by the court.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph V in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

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4. The Divestiture Trustee shall use commercially reasonable 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 and 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 Divestiture 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 Divestiture 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) days of receiving notification of the Commission's approval.

5. The Divestiture 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 Divestiture 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 necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture 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 Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the

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Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph V.E.6., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph V.E.5. of this Order.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

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- F. The Commission may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph V.
- H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.

VI.**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of the agreement. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of the Acquirer or to reduce any obligations of Respondent under such agreement.
- B. If any term of the Divestiture Agreement varies from the terms of this Order ("Order Term"), then to the extent that Respondent cannot fully comply with both terms, the Order Term shall determine Respondent's obligations under this Order. Respondent shall not modify, replace, or extend the terms of the Divestiture

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Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

VII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
1. Thirty (30) days from the date this Order is issued and every thirty (30) days thereafter for a period of one (1) year and every ninety (90) days thereafter until Respondent has fully complied with the provisions of Paragraph II.E. of this Order; and
 2. No later than one (1) year after the date this Order is issued and annually thereafter until this Order terminates, and at such other times as the Commission staff may request.
- B. With respect to the divestiture required by Paragraph II. of this Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the RF Power Assets; (ii) a description of all substantive contacts with a proposed acquirer (other than JAC); and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

Decision and Order

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

IX.

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 and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at its expense; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on January 21, 2026.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted from NXP Semiconductors N.V. (“NXP”), subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) designed to remedy the anticompetitive effects resulting from NXP’s proposed acquisition of Freescale Semiconductor Ltd. (“Freescale”).

On March 1, 2015, NXP and Freescale executed an Agreement and Plan of Merger (“Merger Agreement”) pursuant to which NXP will acquire all of Freescale’s common stock in a transaction valued at approximately \$11.8 billion (“Acquisition”). The proposed Acquisition would combine the two largest suppliers of RF power amplifiers. The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate 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, by substantially lessening competition in the worldwide market for RF power amplifiers.

Under the terms of the proposed Decision and Order (“Order”) contained in the Consent Agreement, NXP is required, no later than ten days from the close of the NXP/Freescale transaction, to divest its RF power amplifier assets to Jianguang Asset Management Co., Ltd. (“JAC”). The divestiture package includes a manufacturing facility, manufacturing equipment, intellectual property, and customer and supplier contracts. NXP’s RF power employees, including the leadership of the business, will also transfer to JAC. The Consent Agreement provides JAC with everything needed to compete effectively in the RF power amplifier market.

The Consent Agreement has been placed on the public record for 30 days to solicit 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 Consent Agreement and the comments received, and decide

Analysis to Aid Public Comment

whether it should withdraw from the Consent Agreement, modify it, or make it final.

THE PARTIES

Headquartered in the Netherlands, NXP is a semiconductor developer and manufacturer specializing in high performance mixed signal devices for a variety of industries. NXP designs, manufactures, and sells RF power amplifiers, among other products, through its Secure Interface & Power division.

Headquartered in Austin, Texas, Freescale is a manufacturer of stand-alone semiconductors that perform dedicated power usage functions in a variety of electronic systems for automotive, networking, industrial, and consumer applications. Freescale designs, manufactures, and sells RF power amplifiers through its Radio Frequency division.

THE RELEVANT MARKET AND MARKET STRUCTURE

The relevant line of commerce in which to analyze the effects of the Acquisition is no broader than RF power amplifiers. RF power amplifiers (also referred to as RF power transistors) are high power (>1 watt average output power) semiconductors that increase the strength of radio signals transmitted between electronic devices. The largest application for RF power amplifiers, accounting for roughly 70% of revenues, is wireless infrastructure—i.e., cellular base stations (cell towers). Other applications include aviation, industrial, broadcasting, and non-cellular communications such as land mobile radio, as well as potential future applications for cooking and lighting. RF power transistors are manufactured using specialty process technologies in order to deliver high output power and heat dissipation. The two principal technologies are (i) silicon based laterally-diffused metal oxide semiconductor (“LDMOS”) and (ii) gallium nitride on silicon carbide substrate (“GaN”). LDMOS technology accounts for roughly 90% of RF power amplifiers used in wireless infrastructure. According to customers and other market participants, there are no substitutes for RF power amplifiers.

Analysis to Aid Public Comment

The relevant geographic market for RF power amplifiers is worldwide. The three major RF power amplifier suppliers (see below) manufacture the products in facilities around the world, and ship the products from those facilities to customer locations worldwide. There are currently no regulatory barriers, tariffs, or technical specifications that impede worldwide trade, and transportation costs are low.

The RF power amplifier market is characterized by a limited number of suppliers, including Freescale, the largest supplier with 36.6% of the market, and NXP, the second-largest supplier with 25.1% of the market. Infineon Technologies AG (“Infineon”) is the third largest supplier. Freescale, NXP, and Infineon are the only meaningful suppliers of LDMOS-based RF power amplifiers. Infineon, however, has a significantly smaller RF power portfolio than either Freescale or NXP. Several additional companies supply GaN-based RF power amplifiers only, but have small market shares.

The proposed NXP/Freescale combination would cause a moderately concentrated market for RF power amplifiers to become highly concentrated, increasing the Herfindahl-Hirschman Index from 2,203 to 4,040 (a delta of 1,837). This increase in concentration far exceeds the thresholds set out in the *Horizontal Merger Guidelines* for raising a presumption that the Acquisition would create or enhance market power.

ENTRY

Entry into the RF power amplifier market is not likely to deter or counteract any anticompetitive effects of the proposed Acquisition. Entry is unlikely in light of high capital costs, significant switching costs by customers, and the considerable time it would take for customers to develop trust in a new entrant’s products. The same barriers would apply to an expansion into LDMOS-based RF power amplifiers by companies that currently supply only GaN-based RF power amplifiers.

Analysis to Aid Public Comment

EFFECTS OF THE ACQUISITION

Absent a divestiture, the proposed Acquisition is likely to cause competitive harm in the market for RF power amplifiers. NXP and Freescale compete directly for RF power amplifier sales, and customers benefit from that competition in terms of both pricing and product innovation. Customers describe NXP and Freescale as each other's closest competitors, and the parties appear to view each other the same way. By eliminating the competition between NXP and Freescale, the proposed Acquisition likely would lead to unilateral effects in the form of higher prices and reduced innovation, particularly in the wireless infrastructure segment.

THE CONSENT AGREEMENT

The Consent Agreement restores the competition lost from NXP's proposed acquisition of Freescale by requiring NXP to divest its RF power amplifier business to JAC, a Chinese private equity management fund. The proposed divestiture includes everything needed for JAC to compete effectively in the worldwide market for RF power amplifiers.

Under the Order, NXP is required, no later than ten days from the close of the NXP/Freescale transaction, to divest its RF power amplifier assets to JAC. The assets to be divested include a manufacturing facility located in Cabuyao (Philippines), a building in Nijmegen (the Netherlands) to house management and certain R&D and testing labs, all manufacturing and R&D assets used primarily for the RF power amplifier business, and customer support equipment. Additionally, the divestiture package includes all patents and technologies that are exclusively or predominantly used for the RF power amplifier business, and a royalty-free license to use all other NXP patents and technologies required by that business. Finally, the divestiture package includes the transition of NXP's RF power amplifier employees, including the complete management team, to JAC.

The manufacturing assets in the divestiture package include NXP's RF power amplifier back-end manufacturing assets (including the portion of the Philippines facility dedicated to these

Analysis to Aid Public Comment

products) but not its front-end manufacturing assets. Instead, JAC will outsource its front-end manufacturing to a third-party wafer foundry. In the interim, the Order requires that, at the request of JAC and in a manner approved by the Commission, NXP must provide front-end wafer manufacturing for a period of up to sixty months. Similarly, the Order also requires NXP to provide support services such as logistical and administrative support for a period of up to thirty-six months.

In addition, the Order includes other standard terms designed to ensure the viability of the divested business. NXP must assist JAC in hiring the existing work force of NXP's RF power amplifier business, and must refrain from soliciting those employees for two years. A Monitor will oversee NXP's compliance with the obligations set forth in the Order. If NXP does not fully comply with the divestiture and requirements of the Order, the Commission may appoint a Divestiture Trustee to divest the RF power amplifier assets and perform NXP's other obligations consistent with the Order.

Given the robustness of the divested business and the protections contained in the Order, the divestiture of NXP's RF power amplifier assets to JAC is likely to preserve competition. Potential customers have confirmed that the divested assets include everything necessary to compete effectively as a viable business. Similarly, potential customers have confirmed that JAC would be a workable option as a supplier.

OPPORTUNITY FOR PUBLIC COMMENT

The purpose of this analysis is to facilitate public comment on the Consent Agreement to aid the Commission in determining whether it should make the Consent Agreement final. This analysis is not an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.

Complaint

IN THE MATTER OF

DRUG TESTING COMPLIANCE GROUP, LLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4565; File No. 151 0048
Complaint, January 21, 2016 – Decision, January 21, 2016

This consent order addresses Drug Testing Compliance Group, LLC's communication to a competitor in an attempt to arrange a customer allocation agreement. The complaint alleges that TC Group violated Section 5 of the Federal Trade Commission Act by inviting a competitor to enter a customer allocation agreement. Under the Order respondent DTC Group is required to cease and desist from communicating with its competitors about customers and prices. The Order also prohibits DTC Group from entering into, participating in, inviting, or soliciting an agreement with any competitor to allocate customers, to divide markets, or to fix prices.

Participants

For the *Commission*: *William Lanning*.

For the *Respondent*: *Michelle Points, Points Law, PLLC*.

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 ("Commission"), having reason to believe that Drug Testing Compliance Group, LLC, has violated the provisions of 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 as follows:

NATURE OF THE CASE

1. Drug Testing Compliance Group, LLC ("DTC Group") invited its closest rival to enter into a customer allocation agreement. By inviting collusion, DTC Group endangered competition and violated Section 5 of the FTC Act.

Complaint

RESPONDENT

2. Drug Testing Compliance Group, LLC, is a limited liability corporation organized, existing, and doing business under and by virtue of the laws of Idaho, with its principal place of business in Meridian, Idaho.

3. DTC Group markets and sells to commercial drivers, commercial trucking firms, and other persons an array of services that facilitate compliance with various regulations administered by the Department of Transportation and the Federal Motor Carrier Safety Administration, including services relating to drug and alcohol testing, safety audits, driver qualification files, and other record keeping.

4. DTC Group primarily utilizes telemarketing and the internet to advertise and sell its services. DTC Group competes with several firms throughout the United States offering similar services.

JURISDICTION

5. At all times relevant herein, DTC Group has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

6. The business practices of DTC Group, 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.

INVITATION TO COLLUDE

7. DTC Group and Competitor A market and sell similar services in direct competition. Beginning in 2013 and continuing to date, DTC Group and Competitor A have competed for one another’s customers by offering lower prices for similar services. In some instances, one rival can induce a customer, whose contract is terminable at will, to switch service providers by offering lower prices.

Complaint

8. On or about June 27, 2014, the president of DTC Group, David Crossett, contacted Competitor A to complain about the actions of Competitor A's sales personnel that led a DTC Group customer to switch service providers. Mr. Crossett requested a meeting with Competitor A to discuss the matter.

9. On or about July 10, 2014, Mr. Crossett met with the principals of Competitor A. Mr. Crossett proposed that the firms agree not to solicit or compete for one another's customers. Specifically, Mr. Crossett proposed that DTC Group and Competitor A should reciprocally agree to refrain from selling or attempting to sell a service to a customer if the rival firm had previously arranged to sell the same service to the customer. Mr. Crossett referred to this arrangement as "First Call Wins," and explained that such agreement would allow each company to sell its services to customers without fearing that its rival would later undercut it with a lower price offer.

VIOLATION CHARGED

10. As set forth in Paragraphs 7 through 9 above, DTC Group invited a competitor to enter into an agreement to allocate customers, in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices of DTC Group, 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. Such acts and practices of DTC Group will continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-first day of January 2016, issues its complaint against Drug Testing Compliance Group.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Drug Testing Compliance Group, LLC (hereinafter referred to as “Respondent”), a limited liability corporation, and Respondent having been furnished thereafter with a copy of the 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 Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, Respondent’s attorney, 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 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, 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 Order:

1. Respondent Drug Testing Compliance Group, LLC is a limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Idaho, with its corporate office and principal

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place of business located at 217 East Pine Avenue, Suite 102, Meridian, Idaho 83642.

2. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Drug Testing Compliance Group, LLC, and this proceeding is in the public interest.

ORDER**I.**

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

- A. “Drug Testing Compliance Group” or “Respondent” means Drug Testing Compliance Group, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and any joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Drug Testing Compliance Group, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Relevant Product” means any good or service marketed or sold by the Respondent or any other person that facilitates or assists the purchaser’s compliance with federal regulations of the Department of Transportation and/or the Federal Motor Carrier Safety Administration.
- C. “Commission” means the Federal Trade Commission.
- D. “Competitor” means any person that markets or sells, or could potentially market or sell, any Relevant Product and includes its employees, agents, and representatives.
- E. “Communicating” means any transmittal, exchange, transfer, or dissemination of information, regardless of

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the means by which it is accomplished, and includes all communications, whether written or oral, and all discussions including, but not limited to, meetings, telephone communications, and email.

- F. “Department of Transportation” means the United States Department of Transportation.
- G. “Federal Motor Carrier Safety Administration” means the Federal Motor Carrier Safety Administration of the United States Department of Transportation.

II.

IT IS FURTHER ORDERED that in connection with the sale of any Relevant Product in or affecting commerce, as “commerce” is defined by the Federal Trade Commission Act, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device:

- A. Communicating with any Competitor regarding customers or prospective customers, prices or rates, or prospective prices or rates, of Respondent or any Competitor; *provided, however*, that for purposes of this Paragraph II.A, Communicating does not include the transfer or dissemination of information to the public through websites or other widely accessible methods of advertising such as newspapers, television, signage, direct mail or online and social media.
- B. Entering into, attempting to enter into, adhering to, participating in, maintaining, organizing, implementing, enforcing, inviting, encouraging, offering or soliciting any agreement or understanding, express or implied, between or among Respondent and any Competitor:
 - 1. To allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories;

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2. To raise, fix, maintain, or stabilize prices or price levels, rates or rate levels, or payment terms, or to engage in any other pricing action; or
 3. To set, change, limit or reduce service terms or service levels.
- C. Exhorting, requesting, suggesting, urging, advocating, encouraging, advising, or recommending to any Competitor, either publicly or privately, that such Competitor:
1. Allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories;
 2. Set, change, raise, fix, stabilize or maintain its prices or price levels, rates or rate levels, or payment terms, or engage in any other pricing action; or
 3. Set, change, reduce, limit, maintain, or reduce its service terms or service levels.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, provide to each of Respondent's officers, directors and employees a copy of this Order and the Complaint.
- B. For a period of four (4) years from the date this Order becomes final, provide a copy of this Order and the Complaint to any person who becomes a director, officer, or employee of Respondent, and provide such copies within thirty (30) days of the commencement of such Person's employment or term as an officer or director.

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- C. Require each person to whom a copy of this Order is furnished pursuant to Paragraph III.A. and III.B. above to sign and submit to Respondent within thirty (30) days of the receipt thereof a statement that (1) represents that the undersigned has read and understands the Order, and (2) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject Respondent to penalties for violation of the Order.
- D. Retain documents and records sufficient to record Respondent's compliance with its obligations under Paragraph III of this Order.

IV.

IT IS FURTHER ORDERED that Respondent shall file a verified written report within sixty (60) days from the date this Order becomes final, annually thereafter for four (4) 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, among other information that may be necessary:

- A. A copy of the acknowledgement(s) required by III.C. of the Order; and
- B. A detailed description of the manner and form in which Respondent has complied and is complying with this Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission:

- A. Of any change in its principal address or place of business within twenty (20) days of such change in address; and

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- B. At least thirty (30) days prior to:
1. Any proposed dissolution of Respondent;
 2. Any proposed acquisition, merger, or consolidation of Respondent; or
 3. Any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order, upon written request and upon five (5) days' notice, Respondent shall, without restraint or interference, 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 obtain copies of relevant books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent relating to compliance with this Order, which copying services shall be provided at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. The opportunity to interview officers, directors, or employees of Respondent, who may have counsel present, related to compliance with this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on January 21, 2036.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing consent order (“Consent Agreement”) from Drug Testing Compliance Group, LLC (“DTC Group”). The Commission’s Complaint alleges that DTC Group violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by inviting a competitor to enter a customer allocation agreement.

Under the terms of the proposed Consent Agreement, DTC Group is required to cease and desist from communicating with its competitors about customers and prices. The Consent Agreement also prohibits DTC Group from entering into, participating in, inviting, or soliciting an agreement with any competitor to allocate customers, to divide markets, or to fix prices.

The Consent Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will review the Consent Agreement again and the comments received, and will decide whether it should withdraw from the Consent Agreement or make final the accompanying Decision and Order (“Proposed Order”).

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment. It is not intended to constitute an official interpretation of the proposed Consent Agreement and the accompanying Proposed Order or in any way to modify their terms.

I. The Complaint

The allegations of the Complaint are summarized below:

DTC Group markets and sells an array of services to commercial drivers, commercial trucking firms, and other persons that facilitate compliance with various regulations administered by the Department of Transportation and the Federal Motor

Analysis to Aid Public Comment

Carrier Safety Administration, including regulations relating to drug and alcohol testing, safety audits, and driver qualifications.

DTC Group primarily utilizes telemarketing and the internet to market and sell its services. DTC Group competes with several firms throughout the United States offering similar services.

DTC Group and Competitor A market and sell similar services in direct competition. Beginning in 2013 and continuing to date, DTC Group and Competitor A have competed for one another's customers by offering lower prices for the services they sell. In some instances, one firm can induce a customer, whose contract is terminable at will, to switch service providers by offering lower prices.

On or about June 27, 2014, the president of DTC Group, David Crossett, contacted Competitor A to complain that Competitor A's sales personnel had induced a DTC Group customer to switch service providers. Mr. Crossett requested a meeting with Competitor A to discuss the matter.

Mr. Crossett met with the principals of Competitor A on July 10, 2014. Mr. Crossett proposed that the firms agree not to solicit or compete for one another's customers. Specifically, Mr. Crossett proposed that DTC Group and Competitor A should reciprocally agree to refrain from selling or attempting to sell a service to a customer if the rival firm had previously arranged to sell the same service to the customer. Mr. Crossett referred to this arrangement as "First Call Wins," and explained that such agreement would permit each company to sell its services to customers without fearing that its rival would later undercut it with a lower price offer.

II. Analysis

Mr. Crossett's communication to Competitor A is an attempt to arrange a customer allocation agreement between the two companies. The invitation, if accepted, would be a *per se* violation of the Sherman Act.¹ The Commission has long held

¹ *United States v. Coop. Theatres of Ohio, Inc.*, 845 F.2d 1367, 1372 (6th Cir. 1988) ("[A] horizontal agreement between two competitors to refrain from

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that invitations to collude violate Section 5 of the FTC Act, and this is unaltered by the Commission’s recent Statement on Section 5. In that Statement, the Commission explained that unfair methods of competition under Section 5 “must cause, or be likely to cause, harm to competition or the competitive process, taking into account any associated cognizable efficiencies and business justifications.”² Potential violations are evaluated under a “framework similar to the rule of reason.”³ Competitive effects analysis under the rule of reason depends upon the nature of the conduct that is under review.⁴

An invitation to collude is “potentially harmful and . . . serves no legitimate business purpose.”⁵ For this reason, the Commission treats such conduct as “inherently suspect” (that is, presumptively anticompetitive).⁶ This means that an invitation to

seeking business from each other’s existing accounts . . . is plainly a form of customer allocation and, hence, is the type of ‘naked restraint’ which triggers application of the *per se* rule of illegality.”); *United States v. Cadillac Overall Supply Co.*, 568 F.2d 1078 (10th Cir.), *cert. denied*, 437 U.S. 903 (1978).

2 Fed. Trade Comm’n, Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act (Aug. 13, 2015) (Section 5 Unfair Methods of Competition Policy Statement), *available at* https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf. Commissioner Ohlhausen dissented from the issuance of the Section 5 Unfair Methods of Competition Policy Statement. *See* <https://www.ftc.gov/public-statements/2015/08/dissenting-statement-commissioner-ohlhausen-ftc-act-section-5-policy>.

3 Section 5 Unfair Methods of Competition Policy Statement.

4 *See, e.g., California Dental Ass’n v. FTC*, 526 U.S. 756, 781 (1999) (“What is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.”).

5 *In re Valassis Commc’ns, Inc.*, 141 F.T.C. 247, 283 (2006) (Analysis of Agreement Containing Consent Order to Aid Public Comment); *see also* Address by FTC Chairwoman Edith Ramirez, Section 5 Enforcement Principles, George Washington University Law School at 5 (Aug. 13, 2015), *available at* https://www.ftc.gov/system/files/documents/public_statements/735411/150813section5speech.pdf.

6 *See, e.g., In re North Carolina Bd. of Dental Examiners*, 152 F.T.C. 640, 668 (2011) (noting that inherently suspect conduct is such that can be “reasonably

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collude can be condemned under Section 5 without a showing that the respondent possesses market power.⁷

The Commission has long held that an invitation to collude violates Section 5 of the FTC Act even where there is no proof that the competitor accepted the invitation.⁸ First, unaccepted solicitations may facilitate coordination between competitors because they reveal information about the solicitor's intentions or preferences. Second, it can be difficult to discern whether a competitor has accepted a solicitation. Third, finding a violation may deter similar conduct that has no legitimate business purpose.⁹

characterized as ‘giv[ing] rise to an intuitively obviously inference of anticompetitive effect.’”) (citation omitted).

⁷ See, e.g., *In re Realcomp II, Ltd.*, 148 F.T.C. 137, Docket No. 9320, 2009 FTC LEXIS 250, at *51 (Oct. 30, 2009) (Comm'n Op.) (explaining that if conduct is “inherently suspect” in nature, and there are no cognizable procompetitive justifications, the Commission can condemn it “without proof of market power or actual effects”).

⁸ See, e.g., *In re Valassis Commc'ns, Inc.*, 141 F.T.C. 247 (2006); *In re Stone Container*, 125 F.T.C. 853 (1998); *In re Precision Moulding*, 122 F.T.C. 104 (1996). See also *In re McWane, Inc.*, Docket No. 9351, *Opinion of the Commission on Motions for Summary Decision* at 20-21 (F.T.C. Aug. 9, 2012) (“an invitation to collude is ‘the quintessential example of the kind of conduct that should be . . . challenged as a violation of Section 5’”) (citing the Statement of Chairman Leibowitz and Commissioners Kovacic and Rosch, *In re U-Haul Int'l, Inc.*, 150 F.T.C. 1, 53 (2010)). This conclusion has been endorsed by leading antitrust scholars. See P. Areeda & H. Hovenkamp, VI ANTITRUST LAW ¶ 1419 (2003); Stephen Calkins, *Counterpoint: The Legal Foundation of the Commission's Use of Section 5 to Challenge Invitations to Collude is Secure*, ANTITRUST, Spring 2000, at 69. In a case brought under a state's version of Section 5, the First Circuit expressed support for the Commission's application of Section 5 to invitations to collude. See *Liu v. Amerco*, 677 F.3d 489 (1st Cir. 2012).

⁹ *In re Valassis Commc'ns, Inc.*, 141 F.T.C. 247, 283 (2006) (Analysis of Agreement Containing Consent Order to Aid Public Comment).

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III. The Proposed Consent Order

The Proposed Order has the following substantive provisions:

Section II, Paragraph A of the Proposed Order enjoins DTC Group from communicating with its competitors about rates or prices, with a proviso permitting public posting of rates.

Section II, Paragraph B prohibits DTC Group from entering into, participating in, maintaining, organizing, implementing, enforcing, inviting, offering, or soliciting an agreement with any competitor to divide markets, to allocate customers, or to fix prices.

Section II, Paragraph C bars DTC Group from urging any competitor to raise, fix, or maintain its price or rate levels, or to limit or reduce service terms or levels.

Sections III-VI of the Proposed Order impose reporting and compliance requirements on DTC Group.

The Proposed Order will expire in 20 years.

Complaint

IN THE MATTER OF

ARCLIGHT ENERGY PARTNERS FUND VI, L.P.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4563; File No. 151 0149
Complaint, December 28, 2015 – Decision, February 4, 2016

This consent order addresses the acquisition by ArcLight Energy Partners Fund VI, L.P. of Gulf Oil Limited Partnership. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition for gasoline and distillate terminaling services in relevant geographic markets within Pennsylvania. The consent order requires ArcLight to divest Gulf's terminals in Altoona, Pittston Township, Mechanicsburg, and Williamsport.

Participants

For the *Commission*: *Michael E. Blaisdell and Jennifer Milici.*

For the *Respondent*: *Kay Lynn Brumbaugh, Andrews Kurth LLP and Deborah Garza, Covington & Burling LLP.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent ArcLight Energy Partners Fund VI, L.P. ("Respondent" or "ArcLight") has agreed to acquire 100% of the interest in Gulf Oil Limited Partnership ("Gulf") from Cumberland Farms, Inc. in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and which, if consummated, 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 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:

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I. THE RESPONDENT

1. Respondent is a limited partnership 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 200 Clarendon Street, 55th Floor, Boston, Massachusetts 02116.

2. Respondent is engaged in, among other things, investing in energy infrastructure and, through its wholly-owned subsidiary, Pyramid LLC, operates light petroleum products terminals in Pennsylvania.

3. Respondent 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 company 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. Pursuant to two contingent agreements (“Agreements”) dated May 15, 2015, Respondent ArcLight, through its wholly-owned subsidiaries Chelsea Petroleum Products I, LLC and Blue Hills Fuels, Inc., proposes to acquire Gulf and certain other assets from Cumberland Farms, Inc. (the “Acquisition”).

III. THE RELEVANT PRODUCT MARKETS

5. For purposes of this complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are gasoline terminaling services and distillate terminaling services.

6. Terminals are critical to the efficient distribution of light petroleum products (“LPPs”). Transporting bulk quantities of LPPs by pipeline to terminals is significantly less expensive on a per gallon basis than trucking LPPs the same distance. Terminals are capable of receiving bulk shipments of LPPs via pipeline, holding LPPs in storage tanks, and loading smaller quantities onto tanker trucks. Tanker trucks transport LPPs from the terminals to retail locations and end-use customers. Terminaling services, or

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“throughputting,” include the off-loading, temporary storage, and dispensing of LPPs into trucks.

7. There is no cost-effective substitute for terminals and the services they provide. Trucking is not an economical alternative due to the high costs associated with trucking LPPs long distances from refineries to retail locations and end-use customers.

8. Gasoline terminaling service customers can only use terminals that meet gasoline-specific environmental regulations. A terminal must have specialized equipment, including vapor recovery units, tanks with internal floating roofs, and ethanol capability to offer gasoline terminaling services. While distillate terminaling customers may be able to use gasoline terminals, the reverse is not possible due to the more stringent regulatory requirements for the storage and handling of gasoline.

IV. THE RELEVANT GEOGRAPHIC MARKETS

9. There are three relevant geographic markets in Pennsylvania in which to analyze the Acquisition: (1) the Altoona market, which encompasses terminals in Altoona; (2) the Scranton market, which encompasses terminals in Pittston Township, and Edwardsville; and (3) the Harrisburg market, which encompasses terminals in Mechanicsburg, Highspire, Northumberland, and Williamsport.

V. MARKET STRUCTURE

Altoona Area Terminaling Services Markets

10. Three firms, including ArcLight and Gulf, operate terminals in the Altoona market. The terminals owned by ArcLight and Gulf offer both gasoline and distillate terminaling services. The third firm does not offer gasoline terminaling services in the relevant market.

11. The Acquisition, if consummated, would eliminate the only competition in the relevant gasoline terminaling services market and result in a monopoly.

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12. The Acquisition would also reduce the number of firms in the Altoona distillate terminaling services market from three to two. Post-acquisition, ArcLight would own the vast majority of the distillate storage capacity in the Altoona market.

Scranton Area Terminaling Services Markets

13. Three firms, including ArcLight and Gulf, operate terminals in the Scranton market. All three firms offer both gasoline and distillate terminaling services.

14. The Acquisition, if consummated, would reduce the number of firms in the relevant markets from three to two. Post-acquisition, ArcLight would own the vast majority of the gasoline and distillate storage capacity in the Scranton market.

Harrisburg Terminaling Services Markets

15. Three firms provide gasoline terminaling services in the Harrisburg market, including ArcLight and Gulf. One additional firm provides distillate terminaling services in the relevant market.

16. The proposed Acquisition would reduce the number of firms providing gasoline terminaling services in the relevant market from three to two. Post-acquisition, ArcLight would own the vast majority of the gasoline storage capacity in the relevant market.

17. The Acquisition, if consummated, would also reduce the number of firms in the market providing distillate terminaling services from four to three. Post-acquisition, ArcLight would own the vast majority of the distillate storage capacity in the Harrisburg market.

V. BARRIERS TO ENTRY

18. Entry into the relevant markets would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Barriers to entry are significant and include high sunk costs associated with the

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construction of a new terminal and the time required to design, build, and permit a new facility. ArcLight has significant excess capacity in the relevant markets, and this capacity would discourage new entry.

VI. EFFECTS OF THE ACQUISITION

19. The effects of the Acquisition, if consummated, may be to substantially lessen competition and tend to create a monopoly in each relevant 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 the following ways, among others:

- a. by increasing the likelihood that Respondent ArcLight would unilaterally exercise market power in each relevant market; and
- b. by increasing the likelihood of collusive or coordinated interaction between any remaining competitors in the relevant markets.

VII. VIOLATIONS CHARGED

20. The Agreement to acquire Gulf through Chelsea Petroleum Products described in Paragraph 4 constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

21. 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of December, 2015, issues its Complaint against Respondent.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission, having initiated an investigation of the proposed acquisition by ArcLight Energy Partners Fund VI, L.P. (“ArcLight” or “Respondent”) of 100% of the partnership interests of Gulf Oil Limited Partnership from Cumberland Farms, Inc., and Respondent having been furnished thereafter with a copy of 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 attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, 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, 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 accepted the 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 to Maintain Assets:

1. Respondent ArcLight Energy Partners Fund VI, L.P. is a limited partnership organized, existing, and doing business under, and by virtue of, the laws of Delaware, with its corporate office and principal place of

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business located at 200 Clarendon Street, 55th Floor, Boston, Massachusetts 02116.

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 HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions shall apply (to the extent any capitalized term appearing in this Order to Maintain Assets is not defined below, the term shall be defined as that term is defined in the Decision and Order contained in the Consent Agreement):

- A. “ArcLight” or “Respondent” means ArcLight Energy Partners Fund VI, L.P., its directors, officers, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates in each case controlled by ArcLight Energy Partners Fund VI, L.P. (including Gulf Oil Limited Partnership, after the Acquisition) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means (i) Arc Logistics or (ii) any other Person that acquires the PA Terminals Assets pursuant to the Decision and Order.
- D. “Acquisition” means the proposed acquisitions described in the (i) Equity Interests Purchase and Sale Agreement by and among Cumberland Farms, Inc., Gulf Acquisition LLC, and Chelsea Petroleum Products I, LLC, dated May 15, 2015 and (ii) Asset Purchase and Sale Agreement by and between

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Cumberland Farms, Inc. and Blue Hills Fuels, LLC, dated May 15, 2015.

- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Confidential Information” means any and all of the following information:
 - 1. all information that is a trade secret under applicable trade secret or other law;
 - 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer hardware, software and computer software and database technologies, systems, structures, and architectures;
 - 3. all information concerning the relevant business (which includes historical and current financial statements, financial projections and budgets, tax returns and accountants’ materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications, client and customer lists and files, contracts, the names and backgrounds of key personnel and personnel training techniques and materials); and
 - 4. all notes, analyses, compilations, studies, summaries and other material to the extent containing or based, in whole or in part, upon any of the information described above;

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Provided, however, that Confidential Information shall not include information that (i) was, is or becomes generally available to the public other than as a result of a breach of this Order; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary, or other obligation restricting disclosure.

- G. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission in this matter following the issuance and service of a final Decision and Order by the Commission.
- H. “Divestiture Agreement” means (i) the PA Terminal Agreement or (ii) any other agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the PA Terminals Assets, including all related ancillary agreements, schedules, exhibits, and attachments thereto.
- I. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the transaction to divest the PA Terminals Assets to Acquirer.
- J. “PA Terminals Assets” means the assets identified in Paragraph I.T. of the Decision and Order.
- K. “PA Terminals Business” means the business of providing temporary storage for light petroleum

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products received via pipeline, marine vessel, tank trucks, rail, or transport trailers, and the re-delivery of such products from storage tanks into tank trucks, rail cars, transport trailers, or pipelines, conducted by Cumberland (through Gulf Oil Limited Partnership) at the Pennsylvania Locations, prior to the Acquisition.

- L. “PA Terminals Employee” means (i) any individual employed by Gulf on a full-time, part-time, or contract basis at each location of the PA Terminals Business at any time as of and after the date of the announcement of the Acquisition and (ii) up to ten individuals employed by Gulf at any other location whose job responsibilities relate or related to the PA Terminals Business; *provided, however*, that PA Terminals Employee shall not include any individuals of Gulf Oil Limited Partnership retained by Cumberland after the Acquisition.
- M. “Pennsylvania Locations” means the Pennsylvania cities of Altoona, Mechanicsburg, Pittston Township, and Williamsport.
- N. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture, or other entity or a governmental body.

II.

IT IS FURTHER ORDERED that during the time period before the Divestiture Date, Respondent shall operate the PA Terminals Business and PA Terminals Assets in the ordinary course of business consistent with past practices as of the date that Respondent announced the Acquisition, including but not limited to, the following responsibilities:

- A. Respondent shall maintain (i) the PA Terminals Business and PA Terminals Assets in substantially the same condition (except for normal wear and tear)

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existing at the time Respondent signs the Consent Agreement, and (ii) relations and good will with suppliers, customers, landlords, creditors, agents, and other having business relationships with the PA Terminals Business and PA Terminals Assets;

- B. Respondent shall provide the PA Terminals Business with sufficient financial and other resources to (i) operate the PA Terminals Business and PA Terminals Assets at least at the current rate of operation and staffing and to carry out, at their scheduled pace, all business plans and promotional activities in place prior to the Acquisition; (ii) perform all maintenance to, and replacements or remodeling of, the assets of the PA Terminals Business in the ordinary course of business and in accordance with past practice and current plans; (iii) carry on such capital projects, physical plant improvements, and business plans as are already underway or planned for which all necessary regulatory and legal approvals have been obtained, including but not limited to, existing or planned renovation, remodeling, or expansion projects; and (iv) maintain the viability, competitiveness, and marketability of the PA Terminals Business and PA Terminals Assets.
- C. Respondent shall preserve the PA Terminals Business and PA Terminals Assets as an ongoing business and not take any affirmative action, or fail to take any action within Respondent's control, as a result of which the viability, competitiveness, and marketability of the PA Terminals Business and PA Terminals Assets would be diminished.

III.

IT IS FURTHER ORDERED that prior to the Divestiture Date, Respondent shall secure all consents, assignments, and waivers or other authorizations from all Persons that are necessary for the divestiture of the PA Terminals Assets; *provided, however*, that Respondent may satisfy this requirement by certifying that

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Acquirer has executed appropriate agreements or obtained necessary authorizations directly with each of the relevant Persons.

IV.**IT IS FURTHER ORDERED** that:

- A. Until the Divestiture Date, Respondent shall staff the PA Terminals Business and PA Terminals Assets with sufficient employees to maintain the viability and competitiveness of the PA Terminals Business and PA Terminals Assets, including but not limited to, providing each PA Terminals Employee with reasonable financial incentives, if necessary, including continuation of all employee benefits and regularly scheduled raises and bonuses, to continue in his or her position pending divestiture of the PA Terminals Assets.
- B. Respondent shall cooperate with and assist Acquirer to evaluate and retain any PA Terminals Employee necessary to operate the PA Terminals Business in substantially the same manner as Cumberland prior to the divestiture, including but not limited to:
 - 1. Not later than fifteen (15) days before the Divestiture Date, Respondent shall (i) identify all PA Terminals Employees, (ii) allow Acquirer to inspect the personnel files and other documentation of all PA Terminals Employees, to the extent permissible under applicable laws, and (iii) allow Acquirer an opportunity to interview any PA Terminals Employee;
 - 2. Respondent shall (i) not offer any incentive to any PA Terminals Employee to decline employment with Acquirer, (ii) remove any contractual impediments that may deter any PA Terminals Employee from accepting employment with Acquirer, including but not limited to, any non-

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compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by Acquirer, and (iii) not otherwise interfere the recruitment, hiring, or employment of any PA Terminals Employee by Acquirer;

3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with Acquirer for any PA Terminals Employee who accepts an offer of employment from Acquirer and (ii) provide each PA Terminals Employee with reasonable financial incentive as necessary to accept offers of employment with Acquirer; and
4. For a period of two (2) years after the PA Terminals Assets are divested, Respondent shall not solicit the employment of any PA Terminals Employee who becomes employed by Acquirer at the time the PA Terminals Assets are divested; *provided, however,* that a violation of this provision will not occur if: (i) the individual's employment has been terminated by Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.

V.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint a Person ("Monitor") to monitor Respondent's compliance with its obligations under this Order.

Order to Maintain Assets

- B. The Commission shall select the Monitor, 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 any proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. Respondent shall enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order and in consultation with the Commission:
1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
 2. Respondent shall (i) insure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order;
 3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may employ, at the cost and expense of Respondent, such consultants, accountants,

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attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his 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 the Monitor's gross negligence or willful misconduct; and
 5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- D. The Monitor shall report in writing to the Commission concerning Respondent's compliance with this Order on a schedule as determined by Commission staff, including a final report after Respondent has completed all obligations required by Paragraph II. of the Decision and Order (not including Paragraph II.D.4.).
- E. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- F. The Monitor's power and duties shall terminate ten (10) business days after the Monitor has completed his

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final report pursuant to Paragraph V.D. of this Order, or at such other time as directed by the Commission.

- G. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld:
1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after notice by the staff of the Commission to Respondent of the identity of any substitute Monitor, then Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor; and
 2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Monitor, enter into an agreement with the substitute Monitor that, subject to the approval of the Commission, confers on the substitute Monitor all the rights, powers, and authority necessary to permit the substitute Monitor to perform his or her duties and responsibilities pursuant to this Order on the same terms and conditions as provided in this Paragraph V.
- H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

VI.

IT IS FURTHER ORDERED that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any

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reason or purpose, any Confidential Information received or maintained by Respondent relating to the PA Terminals Business or PA Terminals Assets; *provided, however*, that Respondent may disclose or use such Confidential Information in the course of:

1. Performing its obligations or as permitted under this Order to Maintain Assets, Decision and Order, or Divestiture Agreement; or
 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the PA Terminals Business or PA Terminals Assets, or as required by law.
- B. If disclosure or use of any Confidential Information is permitted to Respondent's employees or to any other Person under Paragraph VI.A. of this Order, Respondent shall limit such disclosure or use (i) only to the extent such information is required, (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph VI.A., and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.
- C. Respondent shall enforce the terms of this Paragraph VI. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph VI., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

Order to Maintain Assets

VII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and Decision and Order within thirty (30) days from the date Respondent signs the Consent Agreement (as set forth in the Consent Agreement) and every thirty (30) days thereafter until this Order to Maintain Assets terminates.
- B. With respect to any divestiture required by Paragraph II.A. of the Decision and Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the PA Terminals Assets; (ii) a description of all substantive contacts with a proposed acquirer (in the event that the PA Terminals Assets are divested pursuant to Paragraph II.A.1. of the Decision and Order); and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

VIII.

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to (i) preserve the PA Terminals Business and PA Terminals Assets as a viable, competitive, and ongoing business until the divestiture required by the Decision and Order is achieved; (ii) prevent interim harm to competition pending the relevant divestiture and other relief; and (iii) help remedy any anticompetitive effects of the proposed Acquisition as alleged in the Commission's Complaint.

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IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent 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 Respondent related to compliance with this Order to Maintain Assets, which copying services shall be provided by Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

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XI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate:

- 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 date that Respondent completes the divestiture required by Paragraph II.A. of the Decision and Order; *provided, however*, that if at the time such divestiture has been completed, the Decision and Order in this matter is not yet final, then this Order to Maintain Assets shall terminate three (3) business days after the Decision and Order becomes final.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by ArcLight Energy Partners Fund VI, L.P. (“ArcLight” or “Respondent”) of 100% of the partnership interests of Gulf Oil Limited Partnership from Cumberland Farms, Inc. (“Cumberland”) and Respondent having been furnished thereafter with a copy of 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

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Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, 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 its 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 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 enters the following Decision and Order (“Order”):

1. Respondent ArcLight Energy Partners Fund VI, L.P. is a limited partnership organized, existing, and doing business under, and by virtue of, the laws of Delaware, with its corporate office and principal place of business located at 200 Clarendon Street, 55th Floor, Boston, Massachusetts 02116.
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.

Decision and Order

ORDER**I.**

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

- A. “ArcLight” or “Respondent” means ArcLight Energy Partners Fund VI, L.P., its directors, officers, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates in each case controlled by ArcLight Energy Partners Fund VI, L.P. (including Gulf Oil Limited Partnership, after the Acquisition) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means (i) Arc Logistics or (ii) any other Person that acquires the PA Terminals Assets pursuant to this Order.
- D. “Acquisition” means the proposed acquisitions described in the (i) Equity Interests Purchase and Sale Agreement by and among Cumberland Farms, Inc., Gulf Acquisition LLC, and Chelsea Petroleum Products I, LLC, dated May 15, 2015 and (ii) Asset Purchase and Sale Agreement by and between Cumberland Farms, Inc. and Blue Hills Fuels, LLC, dated May 15, 2015.
- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “ArcLight Terminal Assets” means an option to acquire the Williamsport terminal assets located at 1606 and 2080 Sylvan Road, Armstrong Township, Lycoming County, Pennsylvania; Tax parcel nos. 02-3500-0156B-000 and 02-3500-0158-000.

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- G. “Arc Logistics” means Arc Logistics Partners LP, a limited partnership organized, existing, and doing business under, and by virtue of, the laws of Delaware, with its corporate office and principal place of business located at 725 Fifth Avenue, 19th Floor, New York, New York 10022.
- H. “Confidential Information” means any and all of the following information:
1. all information that is a trade secret under applicable trade secret or other law;
 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, software and computer software and database technologies, systems, structures, and architectures;
 3. all information concerning the relevant business (which includes historical and current financial statements, financial projections and budgets, tax returns and accountants’ materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications, client and customer lists and files, contracts, the names and backgrounds of key personnel, and personnel training techniques and materials); and
 4. all notes, analyses, compilations, studies, summaries, and other material to the extent containing or based, in whole or in part, upon any of the information described above;

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Provided, however, that Confidential Information shall not include information that (i) was, is, or becomes generally available to the public other than as a result of a breach of this Order; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary, or other obligation restricting disclosure.

- I. “Contract” means any agreement, contract, lease, license agreement, consensual obligation, promise, or undertaking (whether written or oral and whether express or implied), whether or not legally binding.
- J. “Corporate Trade Names” means all trademarks, trade names, service marks, trade dress, logos, corporate names, domain names, emblems, signs or insignia, and other source identifiers whether registered or common law, containing or comprising the brand and mark “Gulf.”
- K. “Cost” means the actual cost of direct labor, including employee benefits, materials, resources, and services, plus the actual cost of any third-party charges.
- L. “Divestiture Agreement” means (i) the PA Terminals Agreement or (ii) any other agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the PA Terminals Assets, including all related ancillary agreements, schedules, exhibits, and attachments thereto.
- M. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the transaction to divest the PA Terminals Assets to Acquirer.

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- N. “Divestiture Trustee” means the Person appointed by the Commission pursuant to Paragraph VI. of this Order.
- O. “Excluded Assets” means:
1. Real property and Tangible Personal Property at locations other than the Pennsylvania Locations; *provided, however*, Excluded Assets shall not include any assets at locations other than the Pennsylvania Locations if included as Tangible Personal Property under Paragraph I.T.2. of this Order;
 2. Corporate Trade Names and portions of website content, domain names, or e-mail addresses that contain Corporate Trade Names;
 3. Software that can readily be purchased or licensed from sources other than Respondent and which has not been materially modified (other than through user preference settings), or enterprise software also used by Respondent to manage and account for businesses acquired in the Acquisition, but not included in the PA Terminals Business; and
 4. Any other assets that are shared with, or also pertain to, other businesses acquired by Respondent in the Acquisition, unless such assets primarily relate to the operation of the PA Terminals Business.
- P. “Gulf” means Gulf Oil Limited Partnership, a limited partnership organized, existing, and doing business under, and by virtue of, the laws of Delaware, with its corporate office and principal place of business located at 100 Crossing Boulevard, Framingham, Massachusetts 01702.
- Q. “Intellectual Property” means all intellectual property, including (i) commercial names, all assumed fictional

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business names, trade names, “doing business as” (d/b/a names), registered and unregistered trademarks, service marks and applications, and tradenames; (ii) all patents, patent applications and inventions and discoveries that may be patentable; (iii) all registered and unregistered copyrights in both published works and unpublished works; (iv) all rights in mask works; (v) all know-how, trade secrets, confidential or proprietary information, customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; and (vi) and all rights in internet web sites and internet domain names presently used.

- R. “License” means a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license and such tangible embodiments of the licensed rights (including, but not limited to, physical and electronic copies) as may be necessary or appropriate to enable Acquirer to use the rights.
- S. “PA Terminals Agreement” means the Asset Purchase and Sale Agreement by and between Chelsea Petroleum Products I, LLC and Arc Terminals Pennsylvania Holdings, LLC, dated December 17, 2015, including all related ancillary agreements, schedules, exhibits, and attachments thereto.
- T. “PA Terminals Assets” means all of Respondent’s right, title, and interest (acquired by ArcLight as a result of the Acquisition) in and to all property and assets, real, personal, or mixed, tangible and intangible, of every kind and description, wherever located, relating to operation of the PA Terminals Business, including, but not limited to:
1. all real property interests (including fee simple interests and real property leasehold interests), including all easements, and appurtenances, together with all buildings and other structures,

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facilities, and improvements located thereon, owned, leased, or otherwise held;

2. all Tangible Personal Property, including any Tangible Personal Property removed from any location of the PA Terminals Business since the date of the announcement of the Acquisition, and not replaced, unless such Tangible Personal Property was removed in the ordinary course of business and has a replacement cost of less than \$5,000;
3. all inventories other than inventories held by a customer;
4. all Contracts and all outstanding offers or solicitations to enter into any Contract, and all rights thereunder and related thereto;
5. all consents, licenses, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, and all pending applications therefor or renewals thereof, to the extent assignable;
6. all data and Records, including client and customer lists and Records, referral sources, research and development reports and Records, production reports and Records, service and warranty Records, equipment logs, operating guides and manuals, financial and accounting Records, creative materials, advertising materials, promotional materials, studies, reports, notices, orders, inquiries, correspondence, and other similar documents and Records, and copies of all personnel Records (to the extent permitted by law);
7. all intangible rights and property, including Intellectual Property owned or licensed (as licensor

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or licensee) by Respondent, going concern value, goodwill, and telephone and telecopy listings;

8. all insurance benefits, including rights and proceeds; and
9. all rights relating to deposits and prepaid expenses, claims for refunds and rights to offset in respect thereof;

Provided, however, that the PA Terminals Assets need not include Respondent's right, title, and interest in the Excluded Assets and, *provided further* that the PA Terminals Assets shall include the ArcLight Terminal Assets.

- U. "PA Terminals Business" means the business of providing temporary storage for light petroleum products received via pipeline, marine vessel, tank trucks, rail, or transport trailers, and the re-delivery of such products from storage tanks into tank trucks, rail cars, transport trailers, or pipelines, conducted by Cumberland (through Gulf Oil Limited Partnership) at the Pennsylvania Locations, prior to the Acquisition.
- V. "PA Terminals Employee" means (i) any individual employed by Gulf on a full-time, part-time, or contract basis at each location of the PA Terminals Business at any time as of and after the date of the announcement of the Acquisition and (ii) up to ten individuals employed by Gulf at any other location whose job responsibilities relate or related to the PA Terminals Business; *provided, however,* that PA Terminals Employee shall not include any individuals of Gulf retained by Cumberland after the Acquisition.
- W. "Pennsylvania Locations" means the Pennsylvania cities of Altoona, Mechanicsburg, Pittston Township, and Williamsport.

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- X. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.
- Y. “Public Record Date” means the date on which the Commission accepts the Consent Agreement and places it on the public record for comment.
- Z. “Record” means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- AA. “Tangible Personal Property” means all machinery, equipment, tools, furniture, office equipment, computer hardware, supplies, materials, vehicles, and other items of tangible personal property (other than inventories) of every kind owned or leased, together with any express or implied warranty by the manufacturers or sellers or lessors of any item or component part thereof and all maintenance records and other documents relating thereto.
- BB. “Terminal Customer” means any Person who has a Contract with Respondent for terminaling services at any of the Pennsylvania Locations in effect as of the Public Record Date.
- CC. “Transitional Assistance” means any (i) administrative assistance (including, but not limited to, order processing, shipping, accounting, and information transitioning services) or (ii) technical assistance with respect to the provision of light petroleum products terminaling services.

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II.**IT IS FURTHER ORDERED** that:

- A. No later than twenty (20) days after the Acquisition Date, Respondent shall divest the PA Terminals Assets, absolutely and in good faith, to Arc Logistics pursuant to the PA Terminals Agreement, *provided, however,* that if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that:
1. Arc Logistics is not an acceptable purchaser of the PA Terminals Assets, then Respondent shall immediately rescind the PA Terminals Agreement, and shall divest the PA Terminals Assets no later than 120 days from the date this Order is issued, absolutely and in good faith, at no minimum price, to a Person that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; or
 2. The manner in which the divestiture to Arc Logistics was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the PA Terminals Assets (that shall be incorporated into a revised PA Terminals Agreement) as the Commission may determine are necessary to satisfy the requirements of this Order.
- B. No later than the Divestiture Date, Respondent shall secure all consents, assignments, and waivers, or other authorizations from all Persons that are necessary for the divestiture of the PA Terminals Assets; *provided, however,* that Respondent may satisfy this requirement by certifying that Acquirer has executed appropriate agreements or obtained necessary authorizations directly with each of the relevant Persons.

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- C. At the request of Acquirer, Respondent shall:
1. For a period of twelve (12) months, provide Transitional Assistance to Acquirer at a price not to exceed Cost and in quality and quantity sufficient to enable Acquirer to operate the PA Terminals Business in substantially the same manner (including the ability to increase sales) as Cumberland prior to the Acquisition;
 2. For a period of two (2) years from the Divestiture Date, utilize the divested terminals at each of the Pennsylvania Locations as a customer in volumes sufficient to maintain the viability of the PA Terminals Assets and PA Terminals Business; and
 3. For a period of five (5) years from the Divestiture Date, supply ethanol and biodiesels and terminaling services for ethanol and biodiesels to Acquirer at Respondent's terminals at the Pennsylvania Locations in quantities as needed by Acquirer;

Provided, however, that Respondent shall perform the obligations set forth in this Paragraph II.C. in a manner that receives the prior approval of the Commission;

Provided further that the terms of such obligations shall be extended at the request of Acquirer, subject to the prior approval of the Commission; and

Provided further that Respondent shall not (i) terminate any agreement relating to such obligations because of a material breach by Acquirer, in the absence of a final order of a court of competent jurisdiction or (ii) seek to limit the damages (such as indirect, special, and consequential damages) which Acquirer would be entitled to receive in the event of Respondent's breach of any such agreement.

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- D. Respondent shall cooperate with and assist Acquirer to evaluate and retain any PA Terminals Employee, including, but not limited to:
1. Not later than fifteen (15) days before the Divestiture Date, Respondent shall (i) identify all PA Terminals Employees, (ii) allow Acquirer to inspect the personnel files and other documentation of all PA Terminals Employees, to the extent permissible under applicable laws, and (iii) allow Acquirer an opportunity to interview any PA Terminals Employee;
 2. Respondent shall (i) not offer any incentive to any PA Terminals Employee to decline employment with Acquirer, (ii) remove any contractual impediments that may deter any PA Terminals Employee from accepting employment with Acquirer, including, but not limited to, any non-compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by Acquirer, and (iii) not otherwise interfere with the recruitment, hiring, or employment of any PA Terminals Employee by Acquirer;
 3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with Acquirer for any PA Terminals Employee who accepts an offer of employment from Acquirer and (ii) provide each PA Terminals Employee with reasonable financial incentive as necessary to accept offers of employment with Acquirer; and
 4. For a period of two (2) years after the PA Terminals Assets are divested, Respondent shall not solicit the employment of any PA Terminals Employee who becomes employed by Acquirer at the time the PA Terminals Assets are divested;

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provided, however, that a violation of this provision will not occur if: (i) the individual's employment has been terminated by Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.

- E. With respect to any Intellectual Property that is:
1. Retained by Respondent under Paragraph I.O.4. of this Order, Respondent shall grant a License to Acquirer under such Intellectual Property sufficient for Acquirer to operate the PA Terminals Business in substantially the same manner as Cumberland prior to the Acquisition with the freedom to extend existing services and develop new services; and
 2. Included in the PA Terminals Assets that also relates to operation of any other business that Respondent acquired in the Acquisition, Respondent may enter into an agreement with Acquirer for a License back under such Intellectual Property for use in such other business;

Provided, however, that any License required or permitted under this Paragraph II.E. shall be provided in a manner that receives the prior approval of the Commission.

- F. The purpose of the divestiture of the PA Terminals Assets is to ensure the continued use of the assets in the same businesses in which such assets were engaged at the time of the announcement of the Acquisition by Respondent and to remedy the lessening of competition resulting from the

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Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

- A. For a period of six (6) months after the Divestiture Date, Respondent shall allow any Terminal Customer to terminate its Contract without penalty or charge, upon request of the Terminal Customer.
- B. Respondent shall notify each Terminal Customer of its right to terminate its Contract (i) no later than twenty (20) days after the Public Record Date for Contracts in effect on the Public Record Date; (ii) no later than the execution of the Contract for Contracts that Respondent enters into or renews after the Public Record Date; and (iii) in substantially the same form as the notification attached to this Order as Appendix A.

IV.

IT IS FURTHER ORDERED that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Information received or maintained by Respondent relating to the PA Terminals Business or PA Terminals Assets; *provided, however*, that Respondent may disclose or use such Confidential Information in the course of:
 - 1. Performing its obligations or as permitted under this Order, the Order to Maintain Assets, or Divestiture Agreement; or
 - 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions

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threatened or brought against the PA Terminals Business or PA Terminals Assets, or as required by law.

- B. If disclosure or use of any Confidential Information is permitted to Respondent's employees or to any other Person under Paragraph IV.A. of this Order, Respondent shall limit such disclosure or use (i) only to the extent such information is required; (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph IV.A.; and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.
- C. Respondent shall enforce the terms of this Paragraph IV. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph IV., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

V.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint a Person ("Monitor") to monitor Respondent's compliance with its obligations under this Order.
- B. The Commission shall select the Monitor, 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 any proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor,

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Respondent shall be deemed to have consented to the selection of the proposed Monitor.

- C. Respondent shall enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order and in consultation with the Commission:
1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
 2. Respondent shall (i) insure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order;
 3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may 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 Monitor's duties and responsibilities;
 4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in

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connection with, the performance of his 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 the Monitor's gross negligence or willful misconduct; and

5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- D. The Monitor shall report in writing to the Commission concerning Respondent's compliance with this Order on a schedule as determined by Commission staff, including a final report after Respondent has completed all obligations required by Paragraph II. of this Order (not including Paragraph II.D.4.).
 - E. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. The Monitor's power and duties shall terminate ten (10) business days after the Monitor has completed his final report pursuant to Paragraph V.D. of this Order, or at such other time as directed by the Commission.
 - G. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor, subject

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to the consent of Respondent, which consent shall not be unreasonably withheld:

1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after notice by the staff of the Commission to Respondent of the identity of any substitute Monitor, then Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor; and
 2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Monitor, enter into an agreement with the substitute Monitor that, subject to the approval of the Commission, confers on the substitute Monitor all the rights, powers, and authority necessary to permit the substitute Monitor to perform his or her duties and responsibilities pursuant to this Order on the same terms and conditions as provided in this Paragraph V.
- H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

VI.

IT IS FURTHER ORDERED that:

- A. If Respondent has not fully complied with the divestiture and other obligations as required by Paragraph II. of this Order, the Commission may appoint a Divestiture Trustee to divest the PA Terminals Assets and perform Respondent's other obligations in a manner that satisfies the requirements of this Order.

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- B. In the event that the Commission or the Attorney General brings an action pursuant to Section 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 Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to Section 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. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or other action required by the Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondent shall consent to the following terms and

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conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and to take such other action as may be required to divest the Divestiture Assets.
2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the 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 Divestiture Trustee, by the court.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture

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under this Paragraph VI. in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable 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 and 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 Divestiture 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 Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further* that Respondent shall select such entity within five (5) days of receiving notification of the Commission's approval.
5. The Divestiture 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 Divestiture 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 necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture 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 Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the

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Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph VI.E.6., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph VI.E.5. of this Order.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement

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shall not restrict the Divestiture Trustee from providing any information to the Commission.

- F. The Commission may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VI.
- H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.

VII.**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of such agreement. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of Acquirer or to reduce any obligations of Respondent under such agreement.
- B. If any term of the Divestiture Agreement varies from Paragraphs I.-X. of this Order ("Order Term"), then to the extent that Respondent cannot fully comply with

Decision and Order

both terms, the Order Term shall determine Respondent's obligations under this Order. Respondent shall not modify, replace, or extend the terms of the Divestiture Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

VIII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
 - 1. a. Thirty (30) days from the date this Order is issued;
 - b. Every thirty (30) days thereafter until Respondent has fully complied with Paragraphs II.A. and D. of this Order; and
 - c. Every 180 days thereafter until Respondent has fully complied with Paragraph II.C. of this Order; and
 - 2. No later than one (1) year after the date this Order is issued and annually thereafter until this Order terminates, and at such other times as the Commission staff may request.
- B. With respect to any divestiture required by Paragraph II.A.1. of this Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the PA Terminals Assets; (ii) a description of all substantive contacts with a proposed acquirer; and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which

Decision and Order

Respondent completed such divestiture and the date the divestiture was accomplished.

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

X.

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 and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

Decision and Order

XI.

IT IS FURTHER ORDERED that this Order shall terminate on February 4, 2026.

By the Commission.

Appendix A**NOTICE**

To settle concerns arising from ArcLight's acquisition of certain assets of Cumberland Farms, Inc., on [insert date of consent agreement], ArcLight agreed with the staff of the Federal Trade Commission ("FTC") to allow customers that purchase terminaling services for light petroleum products in certain Pennsylvania locations to terminate their contracts with respect to any or all of the services, at the option of the customer, without penalty or charge, immediately upon request of the customer at any time from the [insert Public Record Date] until six (6) months after [insert Divestiture Date].

You are being sent this notice because you are or will be a customer that purchases terminaling services from ArcLight in [insert city and state]. You may read and download a copy of the Order from the FTC at its web site at [web link to Order] as well as other documents relating to the settlement. ArcLight's obligations with respect to contract termination are set out in Paragraph __ of the Order. Capitalized terms used in the Order are defined in Paragraph I. of the Order.

If you wish to terminate your contract with respect to any or all of the terminaling services you purchase from ArcLight, please contact xxxxxxxxxxxx, Tel: xxxxxxxxxxxx, Email: xxxxxxxxxxxx. If you have any questions or concerns about these obligations, you may contact the staff of the Compliance Division, Bureau of

Analysis to Aid Public Comment

Competition, Federal Trade Commission, Washington, D.C., Tel:
202-326-xxxx.

Non-Public Appendix B**PA Terminals Agreement**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted from ArcLight Energy Partners Fund VI, L.P. (“ArcLight”), subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) designed to remedy the anticompetitive effects resulting from ArcLight’s proposed acquisition of Gulf Oil Limited Partnership (“Gulf”) and related assets from Cumberland Farms, Inc. (“Cumberland”). Under the terms of the proposed Decision and Order (“Order”) contained in the Consent Agreement, ArcLight must divest four of Gulf’s terminals located in Pennsylvania – in Mechanicsburg, Altoona, Pittston Township, and Williamsport – to Arc Logistics Partners, LP (“Arc Logistics”).

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the

Analysis to Aid Public Comment

public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and will decide whether it should withdraw from the Consent Agreement, modify it, or make the Order final.

THE PARTIES

ArcLight invests in energy infrastructure. Through its wholly-owned subsidiary, Pyramid LLC, ArcLight owns and operates twelve light petroleum product (“LPP”) terminals in Pennsylvania. ArcLight uses its terminals to meet its own marketing needs and offers terminaling services to third parties for a fee.

Cumberland, one of the largest convenience store operators in the country, operates a petroleum marketing, terminaling, and distribution business through its Gulf subsidiary. Gulf owns and operates twelve LPP terminals in the Northeast, including seven in Pennsylvania. Gulf also uses its terminals to meet its own marketing needs and provides terminaling services to third parties for a fee.

THE PROPOSED ACQUISITION

Pursuant to two contingent Purchase and Sale Agreements dated May 15, 2015, ArcLight proposes to acquire Gulf, and certain other assets, from Cumberland (the “Acquisition”). 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 Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition for gasoline and distillate terminaling services in relevant geographic markets within Pennsylvania.

THE RELEVANT MARKET

Terminals are critical to the efficient distribution of LPPs. Transporting bulk quantities of LPPs via pipeline or marine vessel is significantly less expensive on a per gallon basis than trucking LPPs the same distance. Terminals serve as the delivery points on pipeline and marine routes and are capable of receiving bulk

Analysis to Aid Public Comment

quantities of LPPs, holding LPPs in storage tanks, and loading smaller quantities of LPPs onto tanker trucks for local delivery. Tanker trucks pick up product from the terminals through specialized loading systems and transport LPPs to retail locations and end-use customers. Terminaling services include the off-loading, temporary storage, and dispensing of LPPs into trucks.

The Commission's Complaint alleges that the relevant product markets within which to analyze the Acquisition are gasoline terminaling services and distillates terminaling services. Gasoline terminaling service customers can only use terminals that meet gasoline-specific environmental regulations. A terminal must have specialized equipment, including vapor recovery units and tanks with internal floating roofs, to offer gasoline terminaling services. While distillate terminaling customers may be able to use gasoline terminals, the reverse is not possible due to the more stringent regulatory requirements for the storage and handling of gasoline.

The Commission's Complaint alleges three relevant geographic markets in Pennsylvania in which to assess the competitive effects of the Acquisition: (1) Altoona, which includes terminals in Altoona; (2) Scranton, which includes terminals in Pittston Township and Edwardsville; and (3) Harrisburg, which includes terminals in Northumberland, Williamsport, Mechanicsburg, and Highspire.

The Acquisition would substantially increase concentration in relevant markets that are already highly concentrated. In the Altoona market, ArcLight and Gulf are the only firms that offer gasoline terminaling services, and two of three firms that offer distillate terminaling services. ArcLight and Gulf are two of only three firms that offer gasoline or distillate terminaling services in the Scranton market. In the Harrisburg market, ArcLight and Gulf are two of three firms that offer gasoline terminaling services, and two of four firms that offer distillate terminaling services.

Analysis to Aid Public Comment

EFFECTS OF THE ACQUISITION

The Acquisition would substantially lessen competition for terminaling services in the relevant markets by enabling ArcLight to exercise market power unilaterally, and enhancing the likelihood of collusion or coordinated interaction among the few remaining terminaling services providers. Post-acquisition, ArcLight would be the sole firm offering gasoline terminaling services in Altoona. It would own most of the LPP storage capacity in each of the other relevant markets and would be able to raise terminaling service fees or reduce access to terminaling services unilaterally. The remaining firms have limited ability to accommodate additional throughput customers and would likely be unable to constrain ArcLight from exercising market power. To the extent the remaining firms could offer some limited constraint on ArcLight's ability to exercise market power unilaterally, they are unlikely to do so because the transaction would increase their incentives to coordinate tacitly with ArcLight.

ENTRY CONDITIONS

Entry into the relevant markets would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Barriers to entry are significant and include high sunk costs associated with the construction of a new terminal, and the substantial amount of time required to design, build, and permit a new facility. ArcLight has significant excess capacity in the relevant markets, and this capacity would also discourage new entry.

THE DECISION AND ORDER

The Order resolves the competitive concerns raised by the Acquisition by requiring that ArcLight divest Gulf's terminals in Altoona, Pittston Township, Mechanicsburg, and Williamsport. The Order requires ArcLight to divest to Arc Logistics, or another acquirer approved by the Commission, the four terminals and all associated assets, as well as enter into certain transitional arrangements necessary for the acquirer to become established and compete successfully in the relevant markets. ArcLight is

Analysis to Aid Public Comment

required to divest the terminals within 20 days of closing the Acquisition.

Arc Logistics is a publicly-traded logistics service provider principally engaged in the terminaling, storage, throughput, and transloading of crude oil and LPPs. The company owns twelve LPP terminals in several states, not including Pennsylvania. To ensure that the acquirer has sufficient throughput at the divested terminals while it negotiates contracts with new terminal customers, the Order requires ArcLight to enter a transitional throughput agreement with Arc Logistics, whereby ArcLight commits to throughput certain volumes at Arc Logistics' terminals for two years. The Order also requires ArcLight to supply Arc Logistics with renewable fuels, at Arc Logistics' request, for a period of five years, an option that will help Arc Logistics attract throughput customers. Finally, the Order requires ArcLight to let any customer in the relevant markets out of its terminaling service contract without penalty for a period of six months after the divestiture, allowing Arc Logistics to compete for those customers.

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 Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

MYLAN N.V.

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

Docket No. C-4557; File No. 151 0129
Complaint, November 2, 2015 – Decision, February 19, 2016

This consent order addresses the acquisition by Mylan N.V. of certain assets of Perrigo Company plc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current and future competition in seven generic pharmaceutical markets in the United States. The consent order requires Mylan to divest all of its rights and assets to (1) acyclovir ointment; (2) bromocriptine mesylate tablets; (3) clindamycin phosphate/benzoyl peroxide gel; (4) hydromorphone hydrochloride extended release tablets; (5) liothyronine sodium tablets; (6) polyethylene glycol 3350 over-the-counter oral solution packets; and (7) scopolamine extended release transdermal patches to Alvogen, Inc.

Participants

For the *Commission*: Marc S. Lanoue, Eric Olson, Jasmine Y. Rosner, and David Von Nirschl.

For the *Respondent*: Yonatan Even and Christine Varney, Cravath, Swaine & Moore LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Mylan N.V. (“Mylan”), a company subject to the jurisdiction of the Commission, has made an offer to acquire the voting securities of Perrigo Company plc (“Perrigo”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate 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.

Complaint

§ 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 Mylan N.V. is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317.

2. The Respondent 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 company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. ACQUIRED COMPANY

3. Perrigo is a company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.

4. Perrigo 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 company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

5. On September 14, 2015, Mylan launched a tender offer to acquire all outstanding ordinary shares of Perrigo pursuant to a cash-and-stock offer valued according to public sources at approximately \$27 billion (the “Acquisition”).

Complaint

IV. THE RELEVANT MARKETS

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

- a. acyclovir ointment;
- b. bromocriptine mesylate tablets;
- c. clindamycin phosphate/benzoyl peroxide gel;
- d. hydromorphone hydrochloride extended release tablets;
- e. liothyronine sodium tablets;
- f. polyethylene glycol 3350 over-the-counter (“OTC”) oral solution packets; and
- g. scopolamine extended release transdermal patches.

7. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

8. Acyclovir is used to slow the growth and spread of herpes virus in the body. Two firms, Mylan and Amneal Pharmaceuticals LLC, currently hold approved U.S. Food and Drug Administration (“FDA”) Abbreviated New Drug Applications (“ANDAs”) for generic acyclovir 5% ointment. Allergan plc (“Allergan”) also sells the authorized generic version for acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter the generic acyclovir market in the near future. The Acquisition would reduce the number of likely future suppliers for generic acyclovir 5% ointment.

Complaint

9. Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson's disease, neuroleptic malignant syndrome, and hyperprolactinemia. In the United States, three companies have approved ANDAs for generic bromocriptine mesylate 2.5 mg tablets: Mylan; Perrigo; and Sandoz AG. The Acquisition would reduce the number of firms capable of supplying generic bromocriptine mesylate 2.5 mg tablets from three to two.

10. Clindamycin phosphate 1%/benzoyl peroxide 5% gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. In the United States, only Mylan markets generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received ANDA approval from the FDA and expects to begin supplying generic clindamycin phosphate 1%/benzoyl peroxide 5% gel in the near future. The Acquisition would combine the only two approved ANDA holders for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel.

11. Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. In the United States, only Perrigo and Allergan hold approved ANDAs to sell generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths. Mallinckrodt plc also sells an authorized generic version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter the market in the near future. As a result, the Acquisition would reduce the number of future suppliers of generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths.

12. Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, three suppliers provide 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets: Mylan; Perrigo; and SigmaPharm Laboratories, LLC. The Acquisition would increase concentration in this market and reduce the number of suppliers of 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets from three to two.

Complaint

13. Polyethylene glycol 3350 (“PEG 3350”) is a laxative used to treat occasional constipation. The market for generic PEG 3350 OTC oral solution 17gm packets is highly concentrated with only Mylan, Perrigo, and Gavis Pharmaceuticals, LLC actively supplying the market. The Acquisition would therefore reduce the number of suppliers in this market from three to two.

14. Scopolamine prevents nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG sells a branded scopolamine extended release (1 mg/72 hours) transdermal patch, Transderm Scop. Only Perrigo holds an approved ANDA to sell generic scopolamine extended release (1 mg/72 hours) transdermal patch. Mylan is one of a limited number of suppliers likely to enter this market in the near future. As a result, the Acquisition would reduce the number of likely future suppliers of generic scopolamine extended release (1 mg/72 hours) transdermal patches.

VI. ENTRY CONDITIONS

15. Entry into the relevant markets described in Paragraphs 6 and 7 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition 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 Mylan and Perrigo and reducing the number of independent significant competitors in

Complaint

the markets for generic (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets, thereby: (a) increasing the likelihood that Mylan would be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices; and

- b. by eliminating future competition between Mylan and Perrigo and reducing the number of generic competitors in the markets for (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

17. The Acquisition described in Paragraph 5, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this second day of November, 2015, issues its Complaint against said Respondent.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Respondent” or “Mylan”) of the voting securities of Perrigo Company plc (“Perrigo”), and Respondent having been furnished thereafter with a copy of 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 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 to accept the executed Consent Agreement 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 Maintain Assets:

1. Respondent Mylan N.V. is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process and the Complaint, the Decision and Order,

Order to Maintain Assets

and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317.

2. Perrigo is a company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.
3. The 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 to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Mylan” or “Respondent” means: Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan N.V. (including, without limitation, Mylan Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Perrigo.
- B. “Perrigo” means: Perrigo Company plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company plc, and the

Order to Maintain Assets

respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- E. “Divestiture Product Business(es)” means the Business of the Respondent within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- F. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- G. “Transition Period” means the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondent to cease the marketing, distribution, and sale of the Divestiture Product(s) acquired by that Acquirer; (ii) the date on which the Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).

Order to Maintain Assets

- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that:

- A. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses.

Order to Maintain Assets

Respondent's responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Divestiture Product Business;
2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold in the United States prior to the date the Consent Agreement was signed by the Respondent, at the related High Volume Accounts;
5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and

Order to Maintain Assets

6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
1. for a period of twelve (12) months beginning on the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the

Order to Maintain Assets

time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

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provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and
5. for a period of one (1) year beginning on the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for

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employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent;

provided further, however, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition.

- E. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date, Respondent, in consultation with the Acquirer of a particular Divestiture Product(s) (“relevant Acquirer”), for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale of such Divestiture Products by the relevant Acquirer is not delayed or impaired by the Respondent;
 2. designate employees of Respondent knowledgeable about the marketing, distribution and sale related to each of the Divestiture Products who will be responsible for communicating directly with the relevant Acquirer, and the Interim Monitor (if one has been appointed), for the

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purposes of assisting in the transfer of the Business related to the Divestiture Products to that Acquirer;

3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the relevant Acquirer;
4. continue to market, distribute and sell the Divestiture Products in the United States;
5. beginning on the Acquisition Date, allow the relevant Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to that Acquirer;
6. beginning on the Acquisition Date, provide the relevant Acquirer with a listing of inventory levels (week of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) on a regular basis and in a timely manner;
7. beginning on the Acquisition Date, provide the relevant Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the relevant Acquirer in an efficient and timely manner.

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- F. Pending divestiture of the Divestiture Product Assets, Respondent shall:
1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as permitted by the Orders or as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except: (i) the Acquirer of the particular Divestiture Product Assets; (ii) other Persons authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf the Acquirer); (iii) the Commission; (iv) the Interim Monitor (if any has been appointed); or (v) Persons as are necessary to give effect to the Mylan Limited License;
 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; *provided however*, that, with respect to the Acyclovir Products that are the subject of the Mylan Limited License, this provision shall only apply to the Confidential Business Information

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related to the ongoing marketing or sales of the Acyclovir Products by the Acquirer (*e.g.*, information on purchases made by the Acquirer under any agreement with the Respondent to Contract Manufacture) and shall not apply to historical Confidential Business Information (*i.e.*, such information as is generated prior to the Closing Date); and

4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days after the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- H. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an

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officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- I. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.

The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has

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not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an 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 Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, 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 the Orders and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to

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each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in final form in commercial quantities, in a manner consistent with cGMP, independently of the Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.

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- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondent 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 reasonable 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 gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days after the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VIII.C. of the Decision and Order, and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer or

Order to Maintain Assets

the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in its final form in commercial quantities, in a manner consistent with cGMP, independent of Respondent.

- I. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. 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 this Paragraph.
- L. 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 the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

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IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VIII.C. of the related Decision and Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders. Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VIII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;

Order to Maintain Assets

- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate as of:

- A. the later of the following dates:

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1. three (3) 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;
 2. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed; or
 3. the day after the Product Manufacturing Technology related to each Divestiture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to the provision of the Product Manufacturing Technology are complete;
- B. if the Acquisition does not occur, the Expiration Date;
or
- C. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Respondent” or “Mylan”) of the voting securities of Perrigo Company plc (“Perrigo”), and Respondent having been furnished thereafter with a copy of a draft of

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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 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 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 consideration of public comments, and having modified the Decision and Order in certain respects, 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 Mylan N.V. is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows:

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Corporate Secretary, 1000 Mylan Boulevard,
Canonsburg, Pennsylvania, 15317.

2. Perrigo is a company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.
3. The 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 the Order, the following definitions shall apply:

- A. “Mylan” or “Respondent” means: Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan N.V. (including, without limitation, Mylan Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Perrigo.
- B. “Perrigo” means: Perrigo Company plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.

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- D. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- E. “Acquisition” means Respondent’s acquisition of more than fifty percent (50%) of the voting securities of Perrigo.
- F. “Acquisition Date” means the date on which the Acquisition is consummated.
- G. “Acyclovir Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #202459, and any supplements, amendments, or revisions to this Application. This Product is a topically administered ointment containing, as an active pharmaceutical ingredient, acyclovir at a 5% strength.
- H. “Acyclovir Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Acyclovir Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acyclovir Products.

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- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Alvogen” means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058, or any of Alvogen Group, Inc.’s wholly-owned subsidiaries.
- K. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- L. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.

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- M. “Bromocriptine Mesylate Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #076962, and any supplements, amendments, or revisions to this Application. This Product is an orally administered tablet containing, as an active pharmaceutical ingredient, bromocriptine mesylate at an Eq 2.5mg base strength.
- N. “Bromocriptine Mesylate Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Bromocriptine Mesylate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Bromocriptine Mesylate Products.
- O. “Categorized Assets” means the following assets and rights of Mylan, as such assets and rights are in existence as of the date Mylan signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;
 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 3. all Product Approvals related to the specified Divestiture Product;
 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

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5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;
8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement or the Mylan Limited License;
 - b. to prohibit Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a

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Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by the Respondent);

- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement or the Mylan Limited License; and
 - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
10. all Product Development Reports related to the specified Divestiture Product;
 11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
 12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the

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investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date,
 - a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each month for each High Volume Account for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by Mylan net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and
 - c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average wholesale price; wholesale acquisition cost; and price to Medicare;

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14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers and all single-source excipient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
15. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;
16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
17. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
19. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include the following: (i) documents relating to

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Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- P. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug,

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and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

- Q. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- R. “Clindamycin Phosphate/Benzoyl Peroxide Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #065443, and any supplements, amendments, or revisions to this Application. This Product is a topically administered gel containing, as active pharmaceutical ingredients, benzoyl peroxide and clindamycin phosphate at a 5%; Eq 1% base strength.
- S. “Clindamycin Phosphate/Benzoyl Peroxide Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Clindamycin Phosphate/Benzoyl Peroxide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Clindamycin Phosphate/Benzoyl Peroxide Products.
- T. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- U. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and

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that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* all of the following:

1. information relating to Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the specified Divestiture Product(s);
3. information that is contained in documents, records or books of the Respondent that is provided to an Acquirer by the Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

V. “Contract Manufacture” means each of the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent and in the identical dosage strength, formulation, and presentation as a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a

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Contract Manufacture Product on behalf of an Acquirer.

- W. “Contract Manufacture Product(s)” means the following, individually and collectively:
1. Acyclovir Products;
 2. Bromocriptine Mesylate Products;
 3. Clindamycin Phosphate/Benzoyl Peroxide Products;
 4. Hydromorphone ER Products;
 5. Liothyronine Sodium Products;
 6. Polyethylene Glycol 3350 Products;
 7. Scopolamine Products; and
 8. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients, or packaging materials (including, without limitation, drug vials);

provided however, that with the consent of the Acquirer of the specified Divestiture Product, the Respondent may substitute a Therapeutic Equivalent form of such Product in performance of the Respondent’s agreement to Contract Manufacture.

- X. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining

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any and all approvals, licenses, registrations, or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and/or sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- Y. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- Z. “Divestiture Agreements” means the following agreements:
1. *Asset Purchase Agreement* by and between Mylan N.V. and Alvogen Group, Inc., dated as of September 30, 2015;
 2. *Supply and Technology Transfer Agreement* by and between Mylan Pharmaceuticals Inc. and Alvogen Group, Inc., in the form submitted by the Respondent to the Commission prior to the Order Date, to be executed on the Closing Date; and
 3. all amendments, exhibits, agreements, and schedules attached to and submitted with the foregoing listed agreements;

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provided, however, the Mylan Limited License is not a Divestiture Agreement.

The Divestiture Agreements are contained in Non-Public Appendix I. Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- AA. "Divestiture Product(s)" means the following, individually and collectively:
1. Acyclovir Products;
 2. Bromocriptine Mesylate Products;
 3. Clindamycin Phosphate/Benzoyl Peroxide Products;
 4. Hydromorphone ER Products;
 5. Liothyronine Sodium Products;
 6. Polyethylene Glycol 3350 Products; and
 7. Scopolamine Products.
- BB. "Divestiture Product Assets" means the following, individually and collectively:
1. Acyclovir Product Assets;
 2. Bromocriptine Mesylate Product Assets;
 3. Clindamycin Phosphate/Benzoyl Peroxide Product Assets;
 4. Hydromorphone ER Product Assets;
 5. Liothyronine Sodium Product Assets;

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6. Polyethylene Glycol 3350 Product Assets; and
 7. Scopolamine Product Assets.
- CC. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- DD. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent:
1. to research and Develop the specified Divestiture Product(s) for marketing, distribution or sale within the Geographic Territory;
 2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
 3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
 4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the Geographic Territory;

provided however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by the Respondent prior to the Acquisition, the scope of the rights granted hereunder

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shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

- EE. “Divestiture Product Releasee(s)” means any of the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- FF. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- GG. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- HH. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- II. “Expiration Date” means the earliest of the following dates:
1. the date on which the Respondent withdraws its tender offer for the voting securities of Perrigo;

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2. the date on which Respondent's tender offer for the voting securities of Perrigo expires without extension or amendment by Respondent;
 3. the date on which a Person other than the Respondent acquires fifty (50) percent or more of the voting securities of Perrigo; or
 4. the date five (5) months after the Order Date.
- JJ. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- KK. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- LL. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the specified Divestiture Product; or (iv) the end of the last quarter following the Acquisition or the Closing Date.
- MM. "Hydromorphone ER Product(s)" means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #206722; and any supplements, amendments, or

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revisions to this Application. These Products are extended release orally administered tablets containing, as an active pharmaceutical ingredient, hydromorphone hydrochloride, at the following strengths: 8mg, 12mg, 16mg, and 32mg.

- NN. “Hydromorphone ER Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Hydromorphone ER Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Hydromorphone ER Products.
- OO. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- PP. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- QQ. “Liothyronine Sodium Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #090326; and any supplements, amendments, or revisions to this Application. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, liothyronine sodium, at the following strengths: Eq 0.005mg base, Eq 0.025mg base, and Eq 0.05mg base.
- RR. “Liothyronine Sodium Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Liothyronine Sodium Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Liothyronine Sodium Products.

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- SS. “Manufacturing Designee” means any Person other than the Respondent or Perrigo that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- TT. “Mylan Limited License” means a non-exclusive and non-renewable license to Mylan to the Product Intellectual Property, the Product Manufacturing Technology, the Product Marketing Materials, the content that is displayed on any Website (to the extent any content is not in the public domain), and the Applications related to the Acyclovir Products: (i) to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Acyclovir Product(s) within the Geographic Territory; (ii) to import or export the Acyclovir Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of these Products in the Geographic Territory; and (iii) to use any Confidential Business Information related to the Acyclovir Products, but solely as is necessary to give effect to this license. The Mylan Limited License shall terminate on or before the earlier of the following dates:
1. the date thirty (30) days after the date on which Perrigo or Respondent receives final FDA approval to market a Product that is the Therapeutic Equivalent of the Acyclovir Products; or
 2. the date three (3) years after the Closing Date for the Acyclovir Products.

The Mylan Limited License is contained in Non-Public Appendix I to this Order.

- UU. “NDC Number(s)” means the National Drug Code Number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

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- VV. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- WW. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- XX. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- YY. “Ownership Interest” means any and all rights, title, and interest, present or contingent to hold any of the following:
1. any voting or non-voting stock, share capital, equity, other interests, or beneficial ownership in a specified entity;
 2. any notes or options convertible into any voting or non-voting stock in a specified entity;
 3. assets that comprise fifty (50) percent or more of a specified entity; or
 4. assets that comprise fifty (50) percent or more of a subsidiary of a specified entity.
- ZZ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

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- AAA. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- BBB. “Polyethylene Glycol 3350 Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondent pursuant to the following Application: ANDA #078915; and any supplements, amendments, or revisions to this Application. These Products are orally administered powder (available packaged in either packets or in bulk containers) containing, as an active pharmaceutical ingredient, polyethylene glycol in the following strengths: 17gm/packet, and 17gm/scoopful.
- CCC. “Polyethylene Glycol 3350 Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Polyethylene Glycol 3350 Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Polyethylene Glycol 3350 Products.
- DDD. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- EEE. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals,

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registrations, licenses or authorizations granted in connection with any Application related to that Product.

FFF. “Product Contracts” means all of the following contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the applicable entity’s sales of Products to that Third Party;
2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture

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Product as a finished Product on behalf of the Respondent;

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of the Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and
13. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such

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rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

GGG. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of the Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto

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(including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

HHH. “Product Development Reports” means all of the following:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA-approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA-approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components, and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

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17. manufacturing batch records related to the specified Divestiture Product;
 18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- III. “Product Employee Information” means the following, for each Divestiture Product Core Employee, and as to the extent permitted by Law:
1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the Respondent within ninety (90) days of the execution date of any Remedial Agreement);
 2. with respect to each such employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;
 - c. a specific description of the employee’s responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the Respondent may provide the employee’s most recent performance appraisal;
 - d. the base salary or current wages;
 - e. the most recent bonus paid, aggregate annual compensation for the Respondent’s last fiscal

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year, and current target or guaranteed bonus, if any;

- f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
- g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

- 3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

JJJ. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed or controlled by Respondent as of the Closing Date:

- 1. Patents;
- 2. Product Copyrights;
- 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
- 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the corporate names or

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corporate trade dress of “Mylan” or “Perrigo” or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Mylan, or Perrigo can be identified or defined.

KKK. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Mylan as of the Closing Date:
 - a. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
2. in those instances in which the Respondent or Perrigo (i) is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product

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subject to such NDA is a Retained Product, a full, complete and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

LLL. “Product Manufacturing Employees” means all salaried employees of the Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

MMM. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the

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active pharmaceutical ingredient, excipients or packaging materials; and

3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

NNN. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

OOO. "Product Research and Development Employees" means all salaried employees of Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

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- PPP. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.
- QQQ. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- RRR. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- SSS. “Proposed Acquirer” means a Person proposed by the Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.
- TTT. “Remedial Agreement(s)” means the following:
1. any agreement between the Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;

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2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

UUU. "Retained Product" means any Product(s) other than a Divestiture Product.

VVV. "Right of Reference or Use" means, for the purpose of obtaining approval of an Application or to defend an

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Application, the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

- WWW. “Scopolamine Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #203753; and any supplements, amendments, or revisions to this Application. These Products are transdermally administered extended release films (patches) containing, as an active pharmaceutical ingredient, scopolamine at a strength of 1mg/72-hours.
- XXX. “Scopolamine Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Scopolamine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Scopolamine Products.
- YYY. “Supply Cost” means a cost not to exceed the Respondent’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product,

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“Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.

ZZZ. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

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- a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
- b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

AAAA. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

BBBB. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; Perrigo; or the Acquirer of particular assets or rights pursuant to this Order.

CCCC. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

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II.

IT IS FURTHER ORDERED that, if the Acquisition occurs, all of the following provisions of Paragraph II of this Order shall apply:

DDDD. Not later than thirty (30) days after the Acquisition Date, Respondent shall divest the Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Alvogen pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Alvogen or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Divestiture Product Assets to Alvogen prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Alvogen is not an acceptable purchaser of the Divestiture Product Assets, then Respondent shall immediately rescind the transaction with Alvogen, in whole or in part, as directed by the Commission, and shall divest the Divestiture Product Assets not later than one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondent has divested the Divestiture Product Assets to Alvogen prior to the Order Date, and if, at the time the Commission determines to make this Order final and

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effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets to Alvogen (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

EEEE. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide each Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer determining whether to assume such contracts or agreements.

FFFF. Prior to the Closing Date for each respective Divestiture Product, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondent may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

GGGG. Respondent shall:

1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;

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2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as permitted by this Order or as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;

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5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except: (i) the Acquirer of the particular Divestiture Products; (ii) other Persons authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf the Acquirer); (iii) the Commission; (iv) the Interim Monitor (if any has been appointed); or (v) Persons necessary to give effect to the Mylan Limited License; and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; *provided however*, that, with respect to the Acyclovir Products that are the subject of the Mylan Limited License, this provision shall only apply to the Confidential Business Information related to the ongoing marketing or sales of the Acyclovir Products by the Acquirer (*e.g.*, information on purchases made by the Acquirer under any agreement with the Respondent to Contract Manufacture) and shall not apply to historical Confidential Business Information (*i.e.*, such information as is generated prior to the Closing Date).

HHHH. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall provide, or cause to be provided to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the

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Divestiture Product(s) being acquired by that Acquirer; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to the Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.

III. With respect to each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:

1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products acquired by that Acquirer at Supply Cost, for a period of time sufficient to allow that

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Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent and Perrigo, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the Respondent from Persons other than Respondent or Perrigo;

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by the Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that

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exceed the representations and warranties made by the Respondent to the Acquirer in an agreement to Contract Manufacture;

provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
4. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by the Respondent;

provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;

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5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. in the event Respondent becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA, then Respondent shall provide a Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is a Therapeutic Equivalent of the Contract Manufacture Product where such facility(ies) is still suitable for use for such manufacturing;
8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture; and
9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to

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obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.F.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of the following dates: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) the date five (5) years after the Closing Date;

- JJJ. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to

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Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order or as otherwise permitted by this Order).

KKKK. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

LLLL. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:

1. for a period of twelve (12) months after the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that

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Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”;

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;

provided, however, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

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3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee

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compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and,

5. for a period of one (1) year after the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent;

provided further, however, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition.

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MMMM. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,

1. Respondent shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product except for ordinary wear and tear;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.

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NNNN. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under any of the following:

1. any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of

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marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

OOOO. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

PPPP. For any patent infringement suit filed prior to the Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the

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Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), the Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent's outside counsel related to that Divestiture Product.

QQQQ. Respondent may enter into the Mylan Limited License with the relevant Acquirer, in the form as is approved by the Commission in connection with the Commission's determination to make the Order final and effective;

provided however, that Respondent shall not modify, amend, extend, or renew the Mylan Limited License without the prior approval of the Commission or enter into any subsequent agreement to license the rights that are the subject of the Mylan Limited License without the prior approval of the Commission;

provided further, however, that any payment or fee from the Respondent to the Acquirer under the Mylan Limited License shall not be based, in whole or in part,

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on the actual sales of the Acyclovir Products or the actual profits from these Products.

RRRR. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
2. to create a viable and effective competitor, that is independent of Respondent and Perrigo in the Business of each Divestiture Product within the Geographic Territory; and
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

SSSS. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

TTTT. The Commission shall select the Interim Monitor, 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 a proposed Interim Monitor

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within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

UUUU. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an 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 Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

VVVV. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the 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 the Order and in consultation with the Commission.
2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the

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date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

WWWW. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.

XXXX. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have

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authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

YYYY. Respondent 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 reasonable 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 gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

ZZZZ. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VIII.C., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in its final form in commercial quantities, in a

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manner consistent with cGMP, independent of Respondent.

AAAAA. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

BBBBB. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

CCCCC. 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 this Paragraph.

DDDDD. 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 the Order.

EEEEE. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

FFFFF. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer,

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deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the 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 Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

GGGGG. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

HHHHH. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the

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Divestiture Trustee to effect the divestiture required by this Order.

- III. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee.

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Respondent shall take no action to interfere with or impede the Divestiture 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 Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable 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 and 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 Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however,* that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture 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 Divestiture 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 necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses

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incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

JJJJ. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

KKKKK. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

LLLLL. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

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- A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that the Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- C. If Respondent does not acquire more than fifty (50) percent of the voting securities of Perrigo on or before the Expiration Date, then, not later than twelve (12) months after the Expiration Date, Respondent shall divest, absolutely and in good faith, all of its Ownership Interest in Perrigo in one or more of the following manners:

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1. on the New York Stock Exchange, or such other securities exchange(s) as the voting securities of Perrigo are registered to be traded on;
 2. to Perrigo, *provided however*, that if any part of the consideration received by Respondent from Perrigo is anything other than cash, then the manner of the transaction shall be subject to the prior approval of the Commission; or
 3. to an Acquirer or Acquirers that receive the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission.
- D. Pending the divestiture described in Paragraph VI.A., Respondent shall not, directly or indirectly, do any of the following:
1. acquire any additional Ownership Interest in Perrigo;
 2. exercise dominion or control over, or otherwise seek to influence, the management direction or supervision of the business of Perrigo including, but not limited to, any participation in the formulation, determination or direction of any business decisions of Perrigo;
 3. propose corporate action requiring the approval of Perrigo shareholders;
 4. nominate, or in any other way seek or obtain representation on the Board of Directors of Perrigo;
 5. have any of the Respondent's directors, officers, or employees serve simultaneously as an officer or director of Perrigo;
 6. exercise any voting rights attached to any Ownership Interest in Perrigo; *provided, however*,

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that in any matter to be voted on by the shareholders of Perrigo, Respondent shall cast votes related to Respondent's Ownership Interest in each class of Perrigo stock in an amount and manner proportional to the vote of all other votes cast by other Perrigo shareholders entitled to vote on such matter;

7. seek or obtain access to any confidential, proprietary, or other non-public information from Perrigo relating to the research, Development, manufacture, distribution, sale, and marketing of Perrigo's Products; *provided however*, this provision shall not be construed to prohibit the Respondent from:
 - a. seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between the Respondent and Perrigo in accordance with the procedures of the forum before which the dispute is pending. With respect to any such discovery, the Respondent shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any person(s) not necessary to the resolution of such dispute; or
 - b. seeking information from Perrigo as a part of normal due diligence for the purposes of negotiating a transaction with Perrigo; or
 8. take any action or omit to take any action in a manner that would be incompatible with the status of the Respondent as a passive investor in Perrigo.
- E. If Respondent does not acquire more than fifty (50) percent of the voting securities of Perrigo on or before the Expiration Date, then, for a period of three (3)

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years beginning on the Expiration Date, Respondent shall not, without the prior approval of the Commission, do any of the following:

1. acquire, directly or indirectly, any Ownership Interest in Perrigo; or
 2. consummate, directly or indirectly, any merger or other combination with Perrigo.
- F. The purpose of the requirements of Paragraph VI is to ensure that, if the Acquisition does not occur in a timely manner, the Respondent will not seek to exert, or exert influence upon the business operations of Perrigo.

VII.

IT IS FURTHER ORDERED that:

- G. Any Remedial Agreement shall be deemed incorporated into this Order.
- H. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- I. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondent's obligation to the Acquirer pursuant to this Order.
- J. For each Divestiture Product that is a Contract Manufacture Product, Respondent shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in

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commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondent and Perrigo all as soon as reasonably practicable.

- K. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- L. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VIII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within five (5) days of the Expiration Date, Respondent shall submit to the Commission a letter certifying the date on which the Expiration Date occurred.
- C. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C., II.D.1.,

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II.D.2., II.D.3., II.E., II.F., II.G., II.H., II.I. and II.J., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- D. One (1) year after the Order Date, annually for the next two years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- E. any proposed dissolution of the Respondent;
- F. any proposed acquisition, merger or consolidation of the Respondent; or

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- G. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on February 19, 2026.

By the Commission.

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Mylan N.V. (“Mylan”) that is designed to remedy the anticompetitive effects resulting from Mylan’s acquisition of Perrigo Company plc (“Perrigo”). Under the terms of the proposed Consent Agreement, Mylan is required to divest to Alvogen, Inc. (“Alvogen”) all of its rights and assets to the following generic pharmaceutical products: (1) acyclovir ointment; (2) bromocriptine mesylate tablets; (3) clindamycin phosphate/benzoyl peroxide gel; (4) hydromorphone hydrochloride extended release tablets; (5) liothyronine sodium tablets; (6) polyethylene glycol 3350 over-the-counter (“OTC”) oral solution packets; and (7) scopolamine extended release transdermal patches.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

Analysis to Aid Public Comment

On September 14, 2015, Mylan launched a hostile tender offer to gain a controlling interest in Perrigo. The Commission alleges in its Complaint that the proposed 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 Commission Act, as amended, 15 U.S.C. § 45, by lessening current and future competition in seven generic pharmaceutical markets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

The Products and Structure of the Markets

A generic pharmaceutical drug contains the same active ingredient as the brand name product, but typically at a much more affordable price. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product typically acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, generic suppliers compete only against each other.

Mylan's proposed acquisition of Perrigo will lessen competition in seven concentrated generic pharmaceutical product markets by reducing the number of current or future suppliers competing in each market. The proposed acquisition will reduce current competition in four generic pharmaceutical markets: (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets.

- Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson's disease, neuroleptic malignant syndrome, and hyperprolactinemia. The market for generic 2.5 mg bromocriptine mesylate tablets is highly concentrated with only three current suppliers: Mylan, Perrigo, and Sandoz

Analysis to Aid Public Comment

AG. Absent a remedy, the proposed transaction would consolidate the market from three to two suppliers.

- Clindamycin phosphate/benzoyl peroxide gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. Today, only Mylan supplies the market with generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received FDA approval for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel and is poised to start supplying the market in the near future. As a result, the proposed transaction would reduce the number of generic clindamycin phosphate 1%/benzoyl peroxide 5% gel suppliers from two to one.
- Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, only three suppliers provide generic liothyronine sodium tablets in the 0.005 mg, 0.025 mg, and 0.05 mg strengths: Mylan, Perrigo, and SigmaPharm Laboratories, LLC. The proposed transaction would further consolidate an already highly concentrated market, leaving two suppliers post-transaction.
- Polyethylene glycol 3350, a laxative, is an OTC oral solution packet used to treat occasional constipation. In the 17 gm/packet OTC market, Mylan, Perrigo, and Gavis Pharmaceuticals, LLC, are the only active suppliers in the market. As a result, the proposed transaction would consolidate the number of active suppliers of generic polyethylene glycol 3350 OTC oral solution packets from three to two.

Additionally, the proposed acquisition will reduce future competition in three generic pharmaceutical markets: (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches. In each of these markets, either Mylan or Perrigo is a likely new entrant in the near future. Without a remedy, the proposed acquisition would eliminate an independent entrant into

Analysis to Aid Public Comment

each market, likely depriving customers of the significant cost savings that result when an additional generic supplier enters a concentrated market.

- Acyclovir ointment is a topical product used to slow the growth and spread of the herpes virus. Mylan and Amneal Pharmaceuticals LLC currently hold ANDAs and supply acyclovir 5% ointment. Allergan plc (“Allergan”) also sells an authorized generic version of acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter this market in the near future.
- Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. Perrigo and Allergan hold ANDAs for 8 mg, 12 mg, and 16 mg extended release tablets. In addition, Mallinckrodt plc markets an authorized generic version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter this market in the near future.
- Scopolamine transdermal patches prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG currently markets the branded version, Transderm Scop, which is available as a 1 mg/72 hour extended release transdermal patch. Perrigo holds the only approved ANDA for the generic version of Transderm Scop. Mylan is one of a limited number of other suppliers likely to enter this market in the near future. As there is no generic version of Transderm Scop on the market today, it is likely that the price for scopolamine transdermal patches would significantly decrease with the onset of generic competition. Without a remedy, the proposed acquisition would eliminate the price reductions that would likely have accompanied Mylan’s independent entry into this market.

Analysis to Aid Public Comment

Entry

Entry into each of these generic pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating current or future competition between Mylan and Perrigo in these seven concentrated markets. In each of these markets, Mylan and Perrigo are two of a limited number of current or likely future suppliers in the United States. Market participants characterize each of the markets as a current or likely future commodity market, in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Mylan and Perrigo currently compete likely would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm’s entry. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition’s anticompetitive effects in each relevant market. Under the Consent Agreement, Mylan is required to divest to Alvogen its rights to the seven relevant products. Alvogen is an international pharmaceutical company, with commercial operations in thirty-four countries. Its business focuses on developing, manufacturing, and distributing generic,

Analysis to Aid Public Comment

branded, and OTC pharmaceutical products. Mylan must accomplish the divestitures to Alvogen and relinquish its rights to these products no later than thirty days after the proposed acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and to divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee if Mylan fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan must provide transitional services to Alvogen to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable Mylan employees. Mylan must also provide Alvogen with a supply of the divested products while Mylan transfers manufacturing technology to Alvogen or its designated manufacturer. The goal of the transitional services is to ensure that Alvogen will be able to operate independent of Mylan in the manufacture and sale of the divested products. Nothing in the Consent Agreement, however, precludes Alvogen from sourcing active pharmaceutical ingredients or other divestiture product inputs from Mylan on a negotiated basis.

As Alvogen was unable to perform due diligence on the Perrigo products at issue, Mylan divested its own on-market, generic acyclovir ointment product rather than Perrigo's product in development. Because the competition that is preserved by the

Analysis to Aid Public Comment

proposed Consent Agreement will only occur when the Perrigo product is launched, the proposed Order permits Mylan to retain the right to sell acyclovir ointment through a license from Alvogen until thirty days after Mylan receives approval for the Perrigo ANDA, but for no longer than three years. This provision is designed to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir ointment ANDA but also ensures Mylan's continued incentive to develop and launch the Perrigo product.

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

Complaint

IN THE MATTER OF

**CARROT NEUROTECHNOLOGY, INC.,
ADAM GOLDBERG,
AND
AARON SEITZ**

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

Docket No. C-4567; File No. 142 3132

Complaint, February 22, 2016 – Decision, February 22, 2016

This consent order addresses Carrot Neurotechnology, Inc.’s advertising for the Ulimeyes software application. The complaint alleges that the respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that Ulimeyes substantially improves users’ vision. The consent order prohibits any representation about the health benefits, performance, efficacy, safety, or side effects of any product or service, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Participants

For the *Commission*: Edward Glennon and Karen Mandel.

For the *Respondents*: James Kaminski and Stuart Sorkin,
Hughes Bentzen, PLLC.

COMPLAINT

The Federal Trade Commission, having reason to believe that Carrot Neurotechnology, Inc., a corporation, and Adam Goldberg and Aaron Seitz, individually and as owners and officers of the corporation (collectively, “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 Carrot Neurotechnology, Inc. (“Carrot”) is a California corporation with its principal office or place of

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business at 3995 Prado De Las Frutas, Calabasas, California, 91302.

2. Respondent Adam Goldberg is an owner and officer of Carrot. Individually or in concert with others, he controlled, had the authority to control, or participated in the acts and practices of Carrot, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Carrot.

3. Respondent Aaron Seitz is an owner and officer of Carrot. Individually or in concert with others, he controlled, had the authority to control, or participated in the acts and practices of Carrot, including the acts and practices alleged in this complaint. His principal office or place of business with regard to the acts and practices alleged in this complaint is the same as that of Carrot.

4. Respondents have advertised, labeled, offered for sale, sold, and distributed the Utimeyes software application to consumers. Utimeyes is for use on mobile devices running the iOS or Android operating systems and computers running the Mac or Windows operating systems. According to its website, www.ultimeyesvision.com, Utimeyes is “scientifically shown to improve vision.”

5. 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.

6. Utimeyes is a “device” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. First sold in 2012, Utimeyes is available for purchase and download over the Internet through the Utimeyes website and third party app stores such as the Apple App Store, Google Play Store, and Amazon Appstore. The retail cost of Utimeyes has ranged between \$5.99 and \$9.99. U.S. sales of Utimeyes from January 2012 through June 2015 totaled more than \$350,000.

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8. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Utimeyes, including but not necessarily limited to the attached Exhibits A through I. These materials contain the following statements and depictions, among others:

a. Exhibit A, screen excerpts from Utimeyes website (March 12, 2014) and Exhibit A-1, full list of “Featured Links” extracted from Utimeyes website (March 13, 2014)

Turn Back The Clock On Your Vision

Reverse the effects of aging eyes. Why rely on reading glasses...and a flashlight to read restaurant menus when you don't have to. ULTIMEYES® delivers sharper vision without glasses and dramatically improves the ability to see in dim light.

Achieve Peak Athletic Performance

Improve on-field, on-court and on-track performance with ULTIMEYES®. Check out the articles below and find out what ULTIMEYES® is and what it is did for the UC Riverside baseball team.

ULTIMEYES® is an affordable, natural and simple-to-use interactive game scientifically designed to improve vision.

[. . .]

Featured Links [The website made the following and other representations in the form of hyperlinks to press releases and other media articles, most of which also quoted the individual Respondents.]

- Better baseball batting through brain science
- Apparently, Your Tablet Can Give You Super-Vision
- Better Batters Result from Brain-training Research
[. . .]
- Learning to see better in life and baseball [. . .]
- How To Improve Your Eyesight By Exercising The Brain With ‘Perceptual Learning’

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- Training Gives Baseball Players Superhuman Vision
- Study Reports Brain can be Trained to See Better [. . .]
- Screen time improves eye sight: study [. . .]
- High Tech Training Improves Vision [. . .]
- This App Trains You to See Farther [. . .]
- Using an iPad ‘boosts vision’: Half an hour a day can improve sight by up to a third [. . .]
- ULTIMEYES, an app that trains your brain and improves vision [. . .]
- The iPad Can Improve Eyesight [. . .]
- This Simple App Can Train Your Brain to Have 20/7.5 Vision [. . .]
- See Like a Big-League Slugger
- University of California Reports Findings That ULTIMEYES® Produces Better Vision and Real World Benefits – Published in Current Biology [. . .]
- UltimEyes iPad App Improves Your Vision by Training Your Brain
- Reverse the effects of aging eyes! ULTIMEYES® [. . .]
- Want To Improve Your Vision? 25 Minutes on this App Will Improve Your Vision By 31%
- A neuroscientist has just developed an app that, after repeated use, makes you see farther. Absolutely astonishing and 100% real. [. . .]

b. Exhibit B, screen excerpts from the UltimEyes website (July 31, 2014) (Exhibit C, screen excerpts from the UltimEyes website (Oct. 21, 2014), contains similar representations)

ULTIMEYES®

A simple-to-use interactive game scientifically shown to improve vision.

[Text appears with a depiction of 3 athletes and 3 executives looking at a series of 3 eye charts, the first blurry, the second more clear, and the third in focus.]

[. . .]

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The Science Behind ULTIMEYES®

ULTIMEYES® optimizes visual processing to reduce blurring. Proprietary algorithms monitor your performance and adapt to it, creating a customized session to ensure optimal progress.

Numerous scientific studies conducted over more than a decade support the principles upon which ULTIMEYES® was created.

ULTIMEYES® is the result of collaboration between Vision Science and Entertainment Software to improve how you see. ULTIMEYES® tailors itself to your unique abilities and is designed to improve visual acuity, contrast sensitivity and attention to yield an overall improvement of your vision. The patent-pending methods of perceptual learning established by Dr. Aaron Seitz, a renowned expert in the field of Perceptual Learning, combined with interactive gaming dynamics proven to engage players, produce high levels of continued focus and, in turn, produces results.

[. . .]

On average, participants in our monitored studies—conducted by University of California researchers—improved by two lines on the eye chart!

Contrast sensitivity, which is the visual skill that enables you to distinguish objects in dim light and against obscure backgrounds, increased dramatically among users in these studies.

[. . .]

Frequently Asked Questions

Click on any question to see its answer.

1. What benefits have ULTIMEYES® users experienced?

ULTIMEYES® users have experienced improvements in different areas of vision, including near vision, far vision, peripheral vision, and contrast sensitivity either monocularly (in one eye) or binocularly (in both eyes).

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2. What are the side effects of ULTIMEYES®?

There are no known side effects from ULTIMEYES®, except better vision.

3. How many ULTIMEYES® sessions are required to improve my vision?

Individuals will notice improvements at different rates. Our research shows that robust improvements in vision are found after completing 32 sessions with some of the individuals noticing some improvement in less than 16 sessions. For maximum benefits we recommend 4 ULTIMEYES® sessions per week, for 8 weeks.

c. Exhibit D, screen excerpt from the Apple App Store (Aug. 12, 2014) (Exhibits E and F, screen excerpts from the Google Play Store (Aug. 14, 2014) and the Amazon Appstore (Aug. 13, 2014), contain similar representations)

**Turn back the clock on your vision

**Lose your reading glasses and delay the need for them

**See better at night

**Read better in dim light

**Improve vision for sports and improved lifestyle

On average ULTIMEYES® clients who completed the ULTIMEYES® program can read two lines better on the Snellen eye chart and experience 100% increase in contrast sensitivity.

Anyone pursuing improved vision through natural means and mitigating the need for visual aids including glasses can benefit from ULTIMEYES®.

ULTIMEYES® works by causing brain plasticity, which is the brain's natural ability to adapt to the environment. What's break-through [sic] about ULTIMEYES® is that it activates brain plasticity to occur in the brain's visual processing center. The

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result is enhanced vision in a completely safe non-invasive and easy to use way.

ULTIMEYES® has been examined in many academic institutions including University of California Los Angeles, University of California Riverside, The Western School of Optometry and other non-academic institutions including law enforcement agencies and athletic organizations by people of all ages, genders and visual abilities. Results of some of these studies have been accepted and will be published by major scientific journals such as Vision Research and Current Biology.

ULTIMEYES® is simple to use. The road to better vision requires you to follow the on-screen prompts and complete four 25-minute sessions per week for a total of eight weeks. Although results vary from person to person many ULTIMEYES® users experience improvement in their vision after only 3 weeks...especially with reading and seeing in dim lighting.

- d. Exhibit G, excerpts from video transcript, “Brain Training Makes Better Batters,” viewable on the Ultimeyes YouTube channel at http://www.youtube.com/watch?v=8M_tVyVlrLQ (published Feb 23, 2014) and on the Amazon Appstore Ultimeyes page (Exhibit F)**

AARON SEITZ, ASSOCIATE PROFESSOR, PSYCHOLOGY: There are, you know, over 100 million people worldwide who have serious vision problems that impact their lives. And, so, if we could use brain training to improve their vision, this has profound benefit to their lives. I decided that I wanted to try to create something which would have real-world impact.

[. . .]

JENNI DEVEAU, POSTDOCTORAL RESEARCHER, PSYCHOLOGY:

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We did a study with the 2013 UCR baseball team where we did vision assessments before their season started and then we conducted training. They came in to our lab. Because they are already started off [sic] with really good vision, we had to really challenge their vision. After the season was over, we had tons of baseball data and searched for the help of Dan Ozer to let us know what does all this mean, what can we do with all this.

DANIEL OZER, PROFESSOR, PSYCHOLOGY: I was able to look at the improvement of the players in terms of more hits, more base on balls, additional bases, and I put that information into a formula that was developed about thirty years ago by a man named Bill James whose methods have become famous in the book Moneyball and was able to see how many runs were created in addition to what you would expect if there had just been normal improvement.

AARON SEITZ: With Dan Ozer, we had discussed that, you know, if they won one extra game based upon this calculation, this would be huge.

DANIEL OZER: And then I placed that into the context of how many runs the UCR pitchers allowed and came up with this estimate of it made a difference of somewhere between four and five games. I was shocked. There has been a lot of interest in the last couple of decades, people with a very serious interest in statistics beginning to look at baseball data because it's runs and runs allowed that win and lose games.

[. . .]

JENNI DEVEAU: Many of the players, they described being able to see things in dimmer light conditions, being able to see the ball better, being able to hit the ball better. They had less strikeouts compared to the rest of the league and they had more runs created.

[. . .]

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TEXT ON SCREEN:

31% IMPROVEMENT IN VISION

4.4% FEWER STRIKEOUTS

41 MORE RUNS

4 TO 5 MORE WINS

[. . .]

AARON SEITZ: What I've been able to do is take my research that started looking at a very simple basic science problem and turn it into a game that anybody could play that has real-world benefits.

e. Exhibit H, Utimeyes Press Release (April 18, 2014)

ULTIMEYES

[. . .]

App Scientifically Shown to Improve Vision is Downloadable Now in the Apple App Store for the iPad and iPhone, and Android Phones via Google Play and Amazon's Appstore for Android

[. . .]

Carrot Neurotechnology, Inc. announced today that its popular vision-enhancing interactive game App, ULTIMEYES®, has launched for all iOS and Android platforms. Previously available only for the PC, Mac and iPad, anyone with an iPhone or Android device can now improve their vision...at home or on the go. Improve the clarity of your vision and ability to see in poor lighting, lessen the need for reading glasses, and improve vision for sports and other everyday activities for a better lifestyle. From athletes who want to sharpen their "perfect vision" to people who struggle with low vision issues, ULTIMEYES® has been scientifically shown to help increase vision capabilities via perceptual learning.

[. . .]

Though results vary from person to person, on average, ULTIMEYES® users that have participated in ULTIMEYES studies could read one or two lines better on the Snellen eye chart and experienced a 100% increase in contrast sensitivity. Studies have been conducted with high performance athletes, law

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enforcement agencies, and people of all ages, genders and vision capabilities.

[. . .]

Carrot Neurotechnology, Inc. develops and sells its patent pending integrated game program ULTIMEYES®, that delivers affordable, safe, and comprehensive vision improvement for sports, reading, driving, and relieving the need for traditional visual aids used for age-related eye conditions such as presbyopia and loss of contrast sensitivity.

f. Exhibit I, Ultimeyes Press Release (Feb. 17, 2014)

University of California Reports Findings That ULTIMEYES® Produces Better Vision and Real World Benefits – Published in Current Biology

A study conducted with UCR Baseball Team [sic] demonstrates that Carrot Neurotechnology Inc.'s interactive vision training game ULTIMEYES® produces improved vision and quantifiable real world benefits.

[. . .]

Carrot Neurotechnology, Inc. today announced that the peer-reviewed journal Current Biology published the results of a study entitled “Improved vision and on-field performance in baseball through perceptual learning,” in the February 17th issue, which demonstrates that improved vision resulting from Carrot Neurotechnology’s integrated interactive game program ULTIMEYES® yields improved vision with real world benefits. In this peer-reviewed journal, the researchers go on to say that the results of the study demonstrate the ability to deliver real world benefits across a broad range of activities ranging from athletics to more routine lifestyle activities such as reading, watching TV and driving.

The study was conducted by the University of California Riverside and the University of California Riverside baseball team prior to the 2013 season and

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included 37 players. As a result of using the integrated interactive game program visual acuity of the trained players increased 31% following use of the program and 7 of the players reached impressive 20/7.5 Snellen acuity. Contrast sensitivity function improved similarly in the trained players. Baseball players typically have excellent vision, so the extent of the improvement surprised the researchers. Players reported, “My eyes feel stronger”, “I can see the ball better while I’m hitting”, “I have greater peripheral vision. Easy to see further”, “I can tell a change in dim light and being able to distinguish lower contrasting things.”

Acuity is the sharpness of vision and contrast sensitivity is the ability to see details in low contrast such as seeing in dim light at night.

[. . .]

“This study reaffirms that our product delivers improved visual performance and confirms that these improvement transfer into practical real-world benefits. We’re encouraged and excited by the broad range of lifestyle benefits that many individuals who rely on vision including athletes but also those with normal vision and low vision going about their routine tasks,” said Adam Goldberg, CEO of Carrot Neurotechnology, Inc.

Count I

Deceptive Efficacy Claims

9. In connection with the advertising, promotion, offering for sale, or sale of Ultimeyes, Respondents have represented, directly or indirectly, expressly or by implication, that Ultimeyes substantially improves users’ vision, including that Ultimeyes:

- a. Improves the vision of users, including people of all ages, genders, and visual abilities;
- b. Improves vision with real world benefits, including benefits across a broad range of activities ranging from

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athletics to more routine lifestyle activities, such as reading, watching TV, and driving;

- c. Improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and
- d. Reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light, and diminishing the need for glasses or other visual aids.

10. The representations set forth in Paragraph 9 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

11. In connection with the advertising, promotion, offering for sale, or sale of Ultimeyes, Respondents have represented, directly or indirectly, expressly or by implication, that scientific testing proves that Ultimeyes:

- a. Improves the vision of users, including people of all ages, genders, and visual abilities;
- b. Improves vision with real world benefits, including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving;
- c. Improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and
- d. Reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light,

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and diminishing the need for glasses or other visual aids.

12. In fact, scientific testing does not prove that Ultimeyes:
- a. Improves the vision of users, including people of all ages, genders, and visual abilities;
 - b. Improves vision with real world benefits, including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving;
 - c. Improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and
 - d. Reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light, and diminishing the need for glasses or other visual aids.
13. Therefore, the representations set forth in Paragraph 11 are false or misleading.

Count III

Deceptive Failure to Disclose Material Connections

14. In numerous instances in connection with the advertising, promotion, offering for sale, or sale of Ultimeyes, Respondents have represented, directly or indirectly, expressly or by implication, that scientific research conducted by Respondent Seitz proves that Ultimeyes improves vision.

15. In numerous instances in which Respondents have made the representation set forth in Paragraph 14 of this complaint, Respondents have failed to disclose, or have failed to disclose adequately, that Respondent Seitz co-owns and is the Chief Scientist of Respondent Carrot. These facts would be material to consumers in their purchase or use decisions regarding Ultimeyes.

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16. Respondents' failure to disclose, or disclose adequately, the material information discussed in Paragraph 15, in light of the representation set forth in Paragraph 14, is a deceptive act or practice.

Violations of Sections 5 and 12

17. The acts and practices of Respondents as alleged in this complaint constitute 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 twenty-second day of February, 2016, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A

- [Skip to main content.](#)
- [UltimEyes®](#)
- [Purchase](#)
- [Activate](#)
- [About](#)
 - [The Science](#)
 - [Benefits](#)
 - [Testimonials](#)
- [FAQ](#)
- [Contact](#)

UltimEyes®

Carrot Neurotechnologies

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\$5.99 for a limited time

Turn Back The Clock On Your Vision

Reverse the effects of aging eyes. Why rely on reading glasses...and a flashlight to read restaurant menus when you don't have to. ULTIMEYES® delivers sharper vision without glasses and dramatically improves the ability to see in dim light.



Achieve Peak Athletic Performance

Improve on-field, on-court and on-track performance with ULTIMEYES®. Check out the articles below and find out what ULTIMEYES® is and what it is did for the UC Riverside baseball team.

ULTIMEYES® is an affordable, natural and simple-to-use interactive game scientifically designed to

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improve vision. [Learn More »](#)

Contact your Authorized Reseller or the ULTIMEYES® team at info@ultimeyesvision.com for more information about ULTIMEYES®

Featured Links

- [Better baseball batting through brain science](#)
- [Apparently, Your Tablet Can Give You Super-Vision](#)
- [Better Batters Result from Brain-training Research](#)
- [UC Riverside Baseball Players Gain Edge, Wins As Part Of Vision Study](#)
- [Learning to see better in life and baseball](#)
- [Vision and the Brain: Can we be Trained to See Better?](#)
- [How To Improve Your Eyesight By Exercising The Brain With 'Perceptual Learning'](#)
- [Training Gives Baseball Players Superhuman Vision](#)
- [Study Reports Brain can be Trained to See Better](#)

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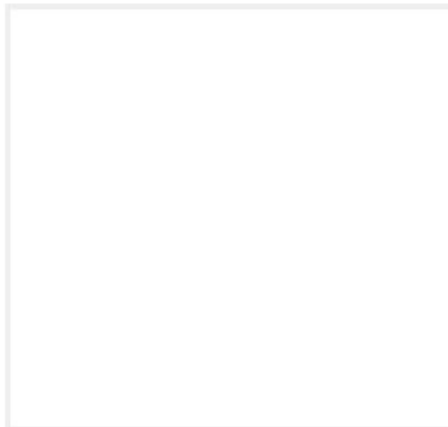
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Contact your Authorized Reseller or the ULTIMEYES® team at info@ultimeyesvision.com (<mailto:info@ultimeyesvision.com>) for more information about ULTIMEYES®

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The Science Behind ULTIMEYES®

ULTIMEYES® optimizes visual processing to reduce blurring. Proprietary algorithms monitor your performance and adapt to it, creating a customized session to ensure optimal progress.

Numerous scientific studies conducted over more than a decade support the principles upon which ULTIMEYES® was created.

ULTIMEYES® is the result of collaboration between Vision Science and Entertainment Software to improve how you see. ULTIMEYES® tailors itself to your unique abilities and is designed to improve visual acuity, contrast sensitivity and attention to yield an overall improvement of your vision. The patent-pending methods of perceptual learning established by Dr. Aaron Seitz, a renowned expert in the field of Perceptual Learning, combined with interactive gaming dynamics proven to engage players, produce high levels of continued focus and, in turn, produces results.

How It Works

ULTIMEYES® strengthens how the brain processes the visual input from the eyes. Patent pending neuroplasticity technology synchronizes task reinforcement with the appropriate stimuli to improve brain plasticity and vision. ULTIMEYES® pairs this breakthrough science with popular game dynamics

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<http://ultimeyesvision.com/science.php>

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ULTIMEYES®

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that heighten levels of engagement and provide the positive reinforcement required to drive progress. In addition, combined audio and visual stimuli ensure that brain plasticity is maximized.

ULTIMEYES® is designed from the ground up to incorporate theory driven, and empirically supported, approaches to vision training into an entertaining video game, by incorporating already proven components along with:

- alerting and orienting cues (sounds spatially located with visual targets)
- training of executive attention (distractors progressively become more similar to tasks targets)
- tasks designed to help with sustained attention (exercises become progressively longer with time)

These approaches, such as multi-sensory stimuli, motivating tasks, and consistent reinforcement to the training stimuli as found in a well-designed video game, are our way of creating a positive outcome for the user.

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About ULTIMEYES®

ULTIMEYES® is a non-invasive interactive program designed specifically to improve vision by optimizing visual processing in just four simple 25-minute sessions per week for a total duration of eight weeks.

Our customers' performance of ULTIMEYES® is monitored by professional ULTIMEYES® vision coaches to ensure maximum effectiveness. Additionally, we make performance data of each session available to your eye-care provider so that he/she can monitor your progress as well.

On average, participants in our monitored studies—conducted by University of California researchers—improved by two lines on the eye chart!

Contrast sensitivity, which is the visual skill that enables you to distinguish objects in dim light and against obscure backgrounds, increased dramatically among users in these studies.

Read More

[The Science Behind ULTIMEYES® \(science.php\)](#)

[Proven Benefits \(science.php\)](#)

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Testimonials from Customers (testimonials.php)

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Frequently Asked Questions

Click on any question to see its answer.

1. What benefits have ULTIMEYES® users experienced?

100% of ULTIMEYES® users have experienced improvements in vision in at least one area, including near vision, far vision, peripheral vision, and contrast sensitivity either monocularly (in one eye) or binocularly (in both eyes).

2. What are the side effects of ULTIMEYES®?

There are no known side effects from ULTIMEYES®, except better vision.

3. How many ULTIMEYES® sessions are required to improve my vision?

Individuals will notice improvements at different rates. Our research shows that robust improvements in vision are found after completing 32 sessions with some of the individuals noticing some improvement in less than 16 sessions. For maximum benefits we recommend 4 ULTIMEYES® sessions per week, for 8 weeks.

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<http://ultimeyesvision.com/faq.php>

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4. Should I wear glasses when using ULTIMEYES®

Our advice is to use ULTIMEYES® under the viewing conditions that you want to perform best in. If you want to see better with prescription lenses then wear lenses, if you want to see how well you can see without lenses you can try without. For example, some people like to attempt activities without glasses or contacts (reading, getting by around the house, some photographers, etc) and ULTIMEYES® can help with this. However, please be aware that ULTIMEYES® does not correct the optics of your eyes. Thus your vision will be best with optical corrections (glasses, contacts, LASIK, etc) combined with brain training.

5. Do I have to use ULTIMEYES® from 2ft or 5ft?

Please use ULTIMEYES® from the same distance in each of your sessions because ULTIMEYES® keeps track of your visual abilities and if you use ULTIMEYES® from different distances each time then it will not provide the correct challenge. The 2ft (near) and 5ft (far) distances are standard recommendations, however, they do not change what stimuli you are shown and you are welcome to choose a different distance if you have a good reason for this. For example, ULTIMEYES® is best when you are using it under the conditions that are similar to the daily visual tasks that you want to engage in. Thus it is reasonable to pick a distance that is consistent with your desired reading distance, or the distance that you normally use your computer.

6. Why do my eyes feel like they got a work-out?

ULTIMEYES® exercises your vision in a way that may be different than you experience in daily life. Thus, just like the first time that you go to the gym, the first time that you use ULTIMEYES® your eyes may feel a bit tired. This experience typically goes away by your third session as your visual system adjusts to its new work-out routine.

7. Can I use ULTIMEYES® in lieu of glasses or retinal surgery?

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ULTIMEYES®

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Some people might find that they don't require their glasses to do things that required their glasses before using ULTIMEYES®, however, this is dependent on each individual's visual capability, including but not limited to factors such as the optics of the eye. It's common for users of ULTIMEYES® to experience improved vision and diminished need for glasses following use, though they might still require glasses for some visual tasks.

8. I'm an athlete, can ULTIMEYES® improve my vision?

Competition requires being at your best. This includes not just physical but also mental abilities. To be at the best of your game, you need to optimize your vision. Some of the benefits to vision that ULTIMEYES® delivers are especially beneficial for athletes or anyone required to perform optimally in challenging dynamic environments. Distinguishing objects against confusing backgrounds such as a ball traveling in front of a crowd in and out of light, quick identification of threats in the periphery, and responding quickly and correctly to these kinds of circumstances are just a few of the visual benefits that athletes can benefit from. ULTIMEYES® is currently in use by athletes at all levels, including collegiate to professional, in both team sports like baseball and football, and individual sports like tennis and motorsports.

9. Why is ULTIMEYES® beneficial after LASIK or cataract surgery?

Visual correction surgery dramatically improves the visual function of the eyes, however, to achieve the very best results, the brain needs to be taught how best to work with your new eyes. ULTIMEYES® is a cutting edge brain-training program that stimulates brain plasticity and will enable your visual processing to adapt optimally to the change in your eyes following surgery. Using ULTIMEYES® will increase your ability to distinguish objects in greater detail.

10. How long is each ULTIMEYES® session?

Each ULTIMEYES® sessions lasts about 25 minutes.

11. How often should I use the ULTIMEYES® program?

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ULTIMEYES®

Page 4 of 6

For maximum benefits we recommend 4 ULTIMEYES® sessions per week, on separate days. Doing multiple ULTIMEYES® sessions on the same day may or may not provide extra benefits, and if you choose to do extra sessions on a given day please do not count them towards our recommended 32 session routine. Also we recommend against doing multiple sessions on the same day during your first week of training. Doing more than 4 sessions per week or more than 32 sessions may provide additional benefit. Research is still pending on how different schedules impacts the benefits that you may receive and our recommendations are based upon what has worked thus far in laboratory studies.

12. What happens if I quit a session early?

Quitting an ULTIMEYES® session early will not save any of your progress on your current session. The next time you open ULTIMEYES®, your last session will be restarted. We do not recommend quitting a session early, each session is only 25 minutes! There is a "pause" option, if you need a quick break.

13. Why is there a calibration at the beginning of each ULTIMEYES® session?

The calibration at the beginning of each ULTIMEYES® session assesses your visual abilities, and sets up the exercises to your appropriate level. It is very important to try your best at the calibration so your vision can improve.

14. What is the purpose of the assessments?

Assessments are provided on a periodic basis so that improvements can be measured and tracked. They also are used to determine your visual skills and the program presents additional visual challenges based upon your scores on the Contrast Sensitivity Assessment. We strongly recommend doing this when given the opportunity. Increased scores reflect improved vision. ULTIMEYES® keeps track of the scores so you can keep track of your improvement. Assessment 1 ('Landolt C') measures the visual skill required to read various size fonts at various levels of contrast, while

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ULTIMEYES®

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Assessment 2 (Contrast Sensitivity Function measurement) measures contrast sensitivity, which is the visual skill of distinguishing objects against a background.

15. Why is ULTIMEYES® becoming more challenging?

ULTIMEYES® adapts itself to your capabilities. In doing so it will set standards that you may find more challenging than previous sessions. This ensures that the program taps into your maximum capabilities, and is constantly working your brain. Don't get frustrated. It's part of our unique methods of improving your vision. Also, from a practical perspective, please make sure that your screen is free of dust and smudges, and that you keep the glare on your screen to an absolute minimum. It makes a big difference!

16. What are the target images?

These are called Gabor images. Studies have shown neurons in the early visual cortex of the brain respond close to optimally to Gabor patterns and these are widely considered to be the building blocks through which the brain constructs its visual perceptions. Training the brain with Gabors is a method of exercising the most basic functions of the visual system.

17. Why is there sound?

Part of our patent pending technology revolves around sound. We have found that making the user acoustically aware as well as visually aware of the target image enhances the interaction, thereby increasing brain functionality.

18. Do I need an Internet connection to use ULTIMEYES®?

You will need to be connected to the Internet to download the ULTIMEYES® program. You can run the ULTIMEYES® sessions without an Internet connection, however we recommend you are connected to the Internet at least once per week. This allows the ULTIMEYES® team to track your progress.

19. Who keeps track of my ULTIMEYES® progress?

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ULTIMEYES®

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After each ULTIMEYES® session, all data will be automatically uploaded to a database. Here the ULTIMEYES® team can see all session information, monitor your progress as well as provide support and coaching.

20. Who can I contact for help with the ULTIMEYES® program?

For any questions, concerns, or problems please email
help@ultimeyesvision.com (mailto:help@ultimeyesvision.com)

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Page 1 of 2

[ULTIMEYES® \(INDEX.PHP\)](#)[PURCHASE \(PURCHASE.PHP\)](#)[ACTIVATE \(ACTIVATE.PHP\)](#)[ABOUT \(ABOUT.PHP\)](#)[FAQ \(FAQ.PHP\)](#)[CONTACT \(CONTACT.PHP\)](#)A yellow button with a black border and the text "Buy Now" in a bold, sans-serif font.**\$5.99 for a limited time**

Christina (daughter age 5)

I am grateful for ULTIMEYES® for helping my daughter with her vision. I would be happy to recommend the program to anybody that needs it, it was very easy to use. Now my daughter's vision went back to normal.

Tina, Age 46

My eyes were getting weaker, and couldn't see my friends clearly over the dinner table. After using ULTIMEYES® for only a couple of weeks I began to see a difference. Less eye strain, and I could now see people clearly. Definitely noticed a difference and the eye chart test proved it!

Cora, Age 45

I did the program over a two month period and could read three lines better on an eye chart from twenty feet away! I found the program easy to use, and actually quite relaxing. Its not like a test, and would recommend it to anyone who wants to try to improve their eyesight.

Jeff, Age 41

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<http://ultimeyesvision.com/testimonials.php>

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As a photographer, I have always had a keen vision, until a while ago when I noticed I was having trouble focusing. It was worse for me at night, particularly while driving. I couldn't read the signs on the freeway or signs at cross streets. It had gotten to the point where I needed glasses. My vision was even worse within three feet. My optometrist recommended ULTIMEYES® as a possibility. I have been using ULTIMEYES® on my iMac from five feet away. The first thing I started noticing was that there were dirt marks on my walls in my house. Subtle—I didn't notice them before—but now I see them everywhere. I realized my ability to discern subtle changes in contrast had improved. I can also read text on the TV at a distance where that was difficult before. I have noticed, that I can read street signs and freeway signs without my driving glasses—that takes a lot of stress. When I went in for an evaluation at my optometrist's office, I was very pleased at testing out with a two-line improvement on my reading chart. In one eye I went from 20/50 to 20/30. I am very happy about this and am continuing with ULTIMEYES®, with a goal of getting both eyes to 20/20 at least... I am very happy with the results and highly recommend ULTIMEYES®.

Testimonials from Athletes

"My eyes feel stronger. They don't get tired as much."

"I can see the ball better while I am hitting."

"I have greater peripheral vision. Easy to see further."

"I can tell a change in dim light and being able to distinguish lower contrasting things."

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<http://ultimeyesvision.com/testimonials.php>

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Exhibit A-1**ULTIMEYES™**

“Today I had my first tangible proof of progress. I was actually able to see text on the screen of my cellphone at arm's length without using my glasses.”

Peter R.



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UltimEyes®

Carrot Neurotechnologies

\$5.99 for a limited time

Turn Back The Clock On Your Vision

Reverse the effects of aging eyes. Why rely on reading glasses...and a flashlight to read restaurant menus when you don't have to. ULTIMEYES® delivers sharper vision without glasses and dramatically improves the ability to see in dim light.



Achieve Peak Athletic Performance

Improve on-field, on-court and on-track performance with ULTIMEYES®. Check out the articles below and find out what ULTIMEYES® is and what it is did for the UC Riverside baseball team.

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ULTIMEYES® is an affordable, natural and simple-to-use interactive game scientifically designed to improve vision. [Learn More »](#)

Contact your Authorized Reseller or the ULTIMEYES® team at info@ultimeyesvision.com for more information about ULTIMEYES®

Featured Links

- [Better baseball batting through brain science](#)
- [Apparently, Your Tablet Can Give You Super-Vision](#)
- [Better Batters Result from Brain-training Research](#)
- [UC Riverside Baseball Players Gain Edge, Wins As Part Of Vision Study](#)
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- [██████████ Vision Training Helps Improve Ballplayers' Hitting](#)
- [██████████ Using an iPad 'boosts vision': Half an hour a day can improve sight by up to a third](#)
- [██████████ WANT to upgrade your vision? There's an app that gives your eyes a workout and retrains your brain to unlock superhuman abilities.](#)
- [██████████ Visual Program Improves Baseball Players' Game](#)
- [██████████ The UltimEyes iPad App might give you superhuman vision that's better than 20/20! \(Dose\)](#)
- [██████████ UltimEyes and the Pursuit of Perfect Vision \(Gear Patrol\)](#)
- [██████████ New app Ultimeyes gives users 'better vision'](#)
- [██████████ UltimEyes iPad App Improves Your Vision by Training Your Brain](#)
- [██████████ ULTIMEYES, an app that trains your brain and improves vision](#)
- [██████████ Ultimeyes App Gives You Super Vision](#)
- [██████████ Ultimeyes : l'application qui booste votre vision à 11/10...](#)
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- [Training Your Brain to Improve Your Vision](#)
- [This Simple App Can Train Your Brain to Have 20/7.5 Vision](#)
- [The App that Trains You to See Farther... or Does It?](#)
- [New Game offers Superhuman Vision](#)
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- [A neuroscientist has just developed an app that, after repeated use, makes you see farther. Absolutely astonishing and 100% real.](#)
- [Training with ULTIMEYES will improve visual acuity and contrast sensitivity allowing hitters to see things clearer and earlier](#)
- [ULTIMEYES by Carrot Neurotechnology, Inc. app detail :: 148Apps :: iPhone Application and Game Reviews and News](#)
- [Ultimeyes Ipad App Improves Your Vision By Training Your Brain](#)

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Exhibit B

ULTIMEYES® PURCHASE ACTIVATE ABOUT FAQ CONTACT EXISTING USERS: [Click here to add a user](#)

ULTIMEYES®

A simple-to-use interactive game scientifically shown to improve vision.

\$5.99 for a limited time

[Buy](#)

available on Windows, Mac, iPad, iPhone and Android devices

"Improve on-field, on-court and on-track performance with ULTIMEYES®. Click to watch the video or read more to learn what ULTIMEYES® do for the UC Riverside baseball team."

[Watch Video](#)

[Overview](#)

"I'm reaching the end of week 2 and this morning I noticed how much easier it is to see that dates on the calendar in my office hanging on a wall on the other side of the office. The numbers were much brighter and less blurry. After 2 weeks I can already see a difference and I'm very much excited to see the improvement after 6 weeks!"

Kabus V.

"Today I had my first tangible proof of progress. I was actually able to see text on the screen of my cellphone at arm's length without using my glasses."

Peter R.

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ULTIMEYES®

A simple-to-use interactive game [scientifically shown](#) to improve vision.

\$5.99 for a limited time

Buy

Available on Windows, Mac, iPad, iPhone and Android devices.



The Science Behind ULTIMEYES®

ULTIMEYES® optimizes visual processing to reduce blurring. Proprietary algorithms monitor your performance and adapt to it, creating a customized session to ensure optimal progress.

Numerous scientific studies conducted over more than a decade support the principles upon which ULTIMEYES® was created.

ULTIMEYES® is the result of collaboration between Vision Science and Entertainment Software to improve how you see. ULTIMEYES® tailors itself to your unique abilities and is designed to improve visual acuity, contrast sensitivity and attention to yield an overall improvement of your vision. The patent-pending methods of perceptual learning established by Dr. Aaron Seltz, a renowned expert in the field of Perceptual Learning, combined with interactive gaming dynamics proven to engage players, produce high levels of continued focus and, in turn, produces results.

How It Works

ULTIMEYES® strengthens how the brain processes the visual input from the eyes. Patent pending neuroplasticity technology synchronizes task reinforcement with the appropriate stimuli to improve brain plasticity and vision. ULTIMEYES® pairs this breakthrough science with popular game dynamics that heighten levels of engagement and provide the positive reinforcement required to drive progress. In addition, combined audio and visual stimuli ensure that brain plasticity is maximized.

ULTIMEYES® is designed from the ground up to incorporate theory driven, and empirically supported, approaches to vision training into an entertaining video game, by incorporating already proven components along with:

- alerting and orienting cues (sounds spatially located with visual targets)
- training of executive attention (distractors progressively become more similar to tasks/targets)
- tasks designed to help with sustained attention (exercises become progressively longer with time)

These approaches, such as multi-sensory stimuli, motivating tasks, and consistent reinforcement to the training stimuli as found in a well-designed video game, are our way of creating a positive outcome for the user.

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ULTIMEYES® PURCHASE ACTIVATE ABOUT FAQ CONTACT EXISTING USERS: [Click here to add a user](#)

Buy ULTIMEYES® now \$5.99 Discounted for a limited time
Available on Windows, Mac, iPad and Android devices.

WINDOWS & MAC

Step #1
Select a username

User Name

Your username will be linked to the ULTIMEYES® database so that we can help you track your vision improvement over time.

Step #2
Enter your contact info:

First Name

Last Name

Email Address

Verify Email Address

Step #3
Choose a payment method:

PROF. WITH CREDIT CARD
(U.S. only)

IPHONE and IPAD

Click to buy

OR~

If you're on your computer go to the App Store on your iPhone or iPad and buy: ULTIMEYES®

AVAILABLE NOW!

ANDROID

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If you're on your computer or phone, go to the App Store on your Android Device and buy: ULTIMEYES®

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ULTIMEYES®

A simple-to-use interactive game **scientifically shown** to improve vision.

Congratulations on your purchase of ULTIMEYES®

You are **one step closer to better vision**. ULTIMEYES® is a noninvasive computer program that is specifically designed to improve your vision with our simple and comprehensive technology that delivers results in a fun rewarding way.

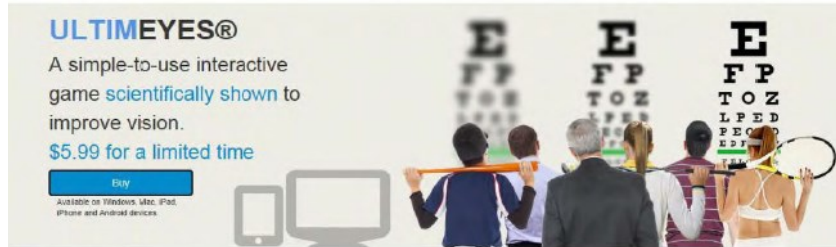
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\$5.99 for a limited time
[Easy](#)
Available on Windows, Mac, iPad, iPhone and Android devices.

About ULTIMEYES®

ULTIMEYES® is a non-invasive interactive program designed specifically to improve vision by optimizing visual processing in just four simple 25-minute sessions per week for a total duration of eight weeks.

Our customers' performance of ULTIMEYES® is monitored by professional ULTIMEYES® vision coaches to ensure maximum effectiveness. Additionally, we make performance data of each session available to your eye-care provider so that he/she can monitor your progress as well.

On average, participants in our monitored studies—conducted by University of California researchers—improved by two lines on the eye chart!

Contrast sensitivity, which is the visual skill that enables you to distinguish objects in dim light and against obscure backgrounds, increased dramatically among users in these studies.

Read More

[The Science Behind ULTIMEYES®](#)

[Testimonials from Customers](#)

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[Buy](#)

Available on Windows, Mac, iPad, iPhone and Android devices.


Frequently Asked Questions

Click on any question to see its answer.

1. What benefits have ULTIMEYES® users experienced?

ULTIMEYES® users have experienced improvements in different areas of vision, including near vision, far vision, peripheral vision, and contrast sensitivity either monocularly (in one eye) or binocularly (in both eyes).

2. What are the side effects of ULTIMEYES®?

There are no known side effects from ULTIMEYES®, except better vision.

3. How many ULTIMEYES® sessions are required to improve my vision?

Individuals will notice improvements at different rates. Our research shows that robust improvements in vision are found after completing 32 sessions with some of the individuals noticing some improvement in less than 16 sessions. For maximum benefits we recommend 4 ULTIMEYES® sessions per week, for 8 weeks.

4. Should I wear glasses when using ULTIMEYES®

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16. What are the target images?

These are called Gabor images. Studies have shown neurons in the early visual cortex of the brain respond close to optimally to Gabor patterns and these are widely considered to be the building blocks through which the brain constructs its visual perceptions. Training the brain with Gabors is a method of exercising the most basic functions of the visual system.

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ULTIMEYES®
 A simple-to-use interactive game **scientifically shown** to improve vision.
\$5.99 for a limited time
 Buy
Available on Windows, Mac, iPad, iPhone and Android devices.

General Inquiries
 For more information about ULTIMEYES®, contact info@ultimeyesvision.com

Address
 Carrot Neurotechnology, Inc.
 23670 Calabasas Rd, Suite 706
 Calabasas, CA 91302-1502

Authorized Dealers
 Interested in becoming an Authorized ULTIMEYES® dealer? Contact us at dealer@ultimeyesvision.com

Problems Purchasing?
 If you are having problems purchasing ULTIMEYES® or using a product activation code, email help@ultimeyesvision.com

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Exhibit C

The screenshot shows a web browser window with the URL <https://ultimeyesvision.com>. The navigation bar includes links for ULTIMEYES®, PURCHASE, ACTIVATE, ABOUT, FAQ, and CONTACT. A link for EXISTING USERS is also present. The main content area features a large advertisement for ULTIMEYES®, described as a simple-to-use vision training app. The ad includes a 'Buy' button, a price of \$9.99, and a note that it is available on Windows, Mac, iPad, iPhone, and Android devices. Below the ad, there is a section for a study report on ULTIMEYES® and a Division 1 NCAA baseball team, with buttons for 'Study Report' and 'ULTIMEYES® Overview'. Two testimonials are provided: one from Kobus V. about seeing dates on a calendar and another from Peter R. about seeing text on a smartphone screen. A 'FEATURED IN:' section lists various media outlets including Yahoo!, BBC, cnet, Popular Mechanics, FOX Sports, Men's Health, THE HUFFINGTON POST, GIZMODO, and Los Angeles Times. At the bottom, there is a social media sharing section with 'Like' and 'Share' buttons and a note that 2,981 people like the page.


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ULTIMEYES® PURCHASE ACTIVATE ABOUT FAQ CONTACT

EXISTING USERS: [Click here to add a user.](#)

Buy ULTIMEYES® now \$9.99 Discounted for a limited time
Available on Windows, Mac, iPad and Android devices.

WINDOWS & MAC



Step #1
Select a username

User Name

Your username will be linked to the ULTIMEYES® database so that we can help you track your vision improvement over time.

Step #2
Enter your contact info:


First Name

Last Name

Email Address


Verify Email Address

Step #3
Choose a payment method.

Check out with  **BUY WITH CREDIT CARD**
(U.S. only)

IPHONE and IPAD

[Click to buy](#)




OR-

If you're on your computer go to the App Store on your iPhone or iPad and buy:
ULTIMEYES®


AVAILABLE NOW!

ANDROID

[Click to buy](#)





And



OR-

If you're on your computer or phone, go to the App Store on your Android Device and buy: ULTIMEYES®

AVAILABLE NOW!

  2,051 people like this. [Sign Up to see what your friends like.](#)

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ULTIMEYES® PURCHASE ACTIVATE ABOUT FAQ CONTACT

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ULTIMEYES®
 A simple-to-use vision training app **scientifically shown** to improve vision
\$9.99
 Buy
 Available on Windows, Mac, iPad, iPhone and Android devices

About ULTIMEYES®

ULTIMEYES® is a non-invasive interactive program designed specifically to improve vision by optimizing visual processing in just four simple 25-minute sessions per week for a total duration of eight weeks.

Our customers' performance of ULTIMEYES® is monitored by professional ULTIMEYES® vision coaches to ensure maximum effectiveness. Additionally, we make performance data of each session available to your eye-care provider so that he/she can monitor your progress as well.

On average, participants in our monitored studies—conducted by University of California researchers—improved by two lines on the eye chart!

Contrast sensitivity, which is the visual skill that enables you to distinguish objects in dim light and against obscure backgrounds, increased dramatically among users in these studies.

Read More

[The Science Behind ULTIMEYES®](#)

[Testimonials from Customers](#)

[Our Privacy Policy](#)

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\$9.99
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The Science Behind ULTIMEYES®

ULTIMEYES® optimizes visual processing to reduce blurring. Proprietary algorithms monitor your performance and adapt to it, creating a customized session to ensure optimal progress.

Numerous scientific studies conducted over more than a decade support the principles upon which ULTIMEYES® was created.

ULTIMEYES® is the result of collaboration between Vision Science and Entertainment Software to improve how you see. ULTIMEYES® tailors itself to your unique abilities and is designed to improve visual acuity, contrast sensitivity and attention to yield an overall improvement of your vision. The patent-pending methods of perceptual learning established by Dr. Aaron Seitz, a renowned expert in the field of Perceptual Learning, combined with interactive gaming dynamics proven to engage players, produce high levels of continued focus and, in turn, produces results.

How It Works

ULTIMEYES® strengthens how the brain processes the visual input from the eyes. Patent pending neuroplasticity technology synchronizes task reinforcement with the appropriate stimuli to improve brain plasticity and vision. ULTIMEYES® pairs this breakthrough science with popular game dynamics that heighten levels of engagement and provide the positive reinforcement required to drive progress. In addition, combined audio and visual stimuli ensure that brain plasticity is maximized.

ULTIMEYES® is designed from the ground up to incorporate theory driven, and empirically supported, approaches to vision training into an entertaining video game, by incorporating already proven components along with:


Complaint

- alerting and orienting cues (sounds spatially located with visual targets)
- training of executive attention (distractors progressively become more similar to tasks targets)
- tasks designed to help with sustained attention (exercises become progressively longer with time)

These approaches, such as multi-sensory stimuli, motivating tasks, and consistent reinforcement to the training stimuli as found in a well-designed video game, are our way of creating a positive outcome for the user.

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Frequently Asked Questions

Click on any question to see its answer.

1. What benefits have ULTIMEYES® users experienced?

ULTIMEYES® users have experienced improvements in different areas of vision, including near vision, far vision, peripheral vision, and contrast sensitivity either monocularly (in one eye) or binocularly (in both eyes).

2. What are the side effects of ULTIMEYES®?

There are no known side effects from ULTIMEYES®, except better vision.

3. How many ULTIMEYES® sessions are required to improve my vision?

Individuals will notice improvements at different rates. Our research shows that robust improvements in vision are found after completing 32 sessions with some of the individuals noticing some improvement in less than 16 sessions. For maximum benefits we recommend 4 ULTIMEYES® sessions per week, for 8 weeks.

4. Should I wear glasses when using ULTIMEYES®?

Our advice is to use ULTIMEYES® under the viewing conditions that you want to perform best in. If you want to see better with prescription lenses then wear lenses, if you want to see how well you can see without lenses you can try without. For example, some people like to attempt activities without glasses or contacts (reading, getting by around the house, some photographers, etc) and ULTIMEYES® can help with this. However, please be aware that ULTIMEYES® does not correct the optics of your eyes. Thus your vision will be best with optical corrections (glasses, contacts, LASIK, etc) combined with brain training.

5. Do I have to use ULTIMEYES® from 2ft or 5ft?

Please use ULTIMEYES® from the same distance in each of your sessions because ULTIMEYES® keeps track of your visual abilities and if you use ULTIMEYES® from different distances each time then it will not provide the correct challenge. The 2ft (near) and 5ft (far) distances are standard recommendations, however, they do not

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change what stimuli you are shown and you are welcome to choose a different distance if you have a good reason for this. For example, ULTIMEYES® is best when you are using it under the conditions that are similar to the daily visual tasks that you want to engage in. Thus it is reasonable to pick a distance that is consistent with your desired reading distance, or the distance that you normally use your computer.

6. Why do my eyes feel like they got a work-out?

ULTIMEYES® exercises your vision in a way that may be different than you experience in daily life. Thus, just like the first time that you go to the gym, the first time that you use ULTIMEYES® your eyes may feel a bit tired. This experience typically goes away by your third session as your visual system adjusts to its new work-out routine.

7. Can I use ULTIMEYES® in lieu of glasses or retinal surgery?

Some people might find that they don't require their glasses to do things that required their glasses before using ULTIMEYES®, however, this is dependent on each individual's visual capability, including but not limited to factors such as the optics of the eye. It's common for users of ULTIMEYES® to experience improved vision and diminished need for glasses following use, though they might still require glasses for some visual tasks.

8. I'm an athlete, can ULTIMEYES® improve my vision?

Competition requires being at your best. This includes not just physical but also mental abilities. To be at the best of your game, you need to optimize your vision. Some of the benefits to vision that ULTIMEYES® delivers are especially beneficial for athletes or anyone required to perform optimally in challenging dynamic environments. Distinguishing objects against confusing backgrounds such as a ball traveling in front of a crowd in and out of light, quick identification of threats in the periphery, and responding quickly and correctly to these kinds of circumstances are just a few of the visual benefits that athletes can benefit from. ULTIMEYES® is currently in use by athletes at all levels, including collegiate to professional, in both team sports like baseball and football, and individual sports like tennis and motorsports.

9. Why is ULTIMEYES® beneficial after LASIK or cataract surgery?

Visual correction surgery dramatically improves the visual function of the eyes, however, to achieve the very best results, the brain needs to be taught how best to work with your new eyes. ULTIMEYES® is a cutting edge brain-training program that stimulates brain plasticity and will enable your visual processing to adapt optimally to the change in your eyes following surgery. Using ULTIMEYES® will increase your ability to distinguish objects in greater detail.

10. How long is each ULTIMEYES® session?

Each ULTIMEYES® sessions lasts about 25 minutes.

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Complaint

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General Inquiries
For more information about ULTIMEYES®, contact info@ultimeyesvision.com

Address
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23679 Calabasas Rd. Suite 796
Calabasas, CA 91302-1502

Authorized Dealers
Interested in becoming an Authorized ULTIMEYES® dealer? Contact us at dealer@ultimeyesvision.com

Support
If you are having problems with ULTIMEYES®, or with the website, please email help@ultimeyesvision.com or call 818-796-3842

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ULTIMEYES® PURCHASE ACTIVATE ABOUT FAQ CONTACT

EXISTING USERS: [Click here to add a user](#)

For Existing ULTIMEYES® Users Only

Share ULTIMEYES on your device with additional users for \$4.99

Please fill out the following form. All fields are required.

New User's First Name:

New User's Last Name:

New User's Email:

New User Name:

Enter the username of the person that you are adding to ULTIMEYES®.

Your License Key:

Choose payment option:

[PayPal](#)

-- Or --

[PAY WITH CREDIT CARD](#)
(U.S. only)

\$4.99 for a limited time.

Please make sure that your device is supported

[Click Here](#)

Download links (Mac, PC, iPad) and license are sent after purchase

[Like](#) [Share](#) 2,991 people like this. Sign up to see what your friends like.

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Exhibit D

ULTIMEYES
Cortel Neurotechnology, Inc.

Download
The app is designed for both iPhone and iPad

Rating: 4★ (22)

LINKS
Developer Website

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Description

- Turn back the clock on your vision
- Use your reading glasses and delay the need for them
- Improve your night vision
- Read better in dim light
- Improve vision for sports and improved lifestyle

On average, ULTIMEYES® clients who completed the ULTIMEYES® program (as read two lines better on this screen eye chart and experiencing 100% increase in contrast sensitivity. Anyone pursuing improved vision through natural means and engaging the need for visual aids including glasses can benefit from ULTIMEYES®.

ULTIMEYES® works by causing brain plasticity which is the brain's natural ability to adapt to the environment. What's break through about ULTIMEYES® is that it activates brain plasticity to occur in the brain's visual processing center. The result is enhanced vision in a completely safe non-invasive and easy to use way.

ULTIMEYES® has been examined in many academic institutions including University of California Los Angeles, University of California Riverside, The Veterans Affairs Medical Center, and several other academic institutions. ULTIMEYES® has been examined and used by some of the world's leading eye care organizations by people of all ages, genders and racial/ethnicities. Results of some of these studies have been accepted and are all published by major scientific journals such as Vision Research and Current Biology.

ULTIMEYES® is simple to use. The road to better vision requires you to follow the on-screen prompts and complete four 20-minute sessions per week for a total of eight weeks. Although results vary from person to person many ULTIMEYES® users experience improvement in their vision after only 3 weeks—especially with reading and seeing in dim lighting.

After completing the recommended regimen the improved vision lasts without requiring use of ULTIMEYES®. Since ULTIMEYES® does not require you to use ULTIMEYES® glasses, you can use ULTIMEYES® whenever you'd like in order to maintain and "boost-up" your vision at any time such as before and during baseball season or when you want to ensure that your vision is being sharpened.

Exh. D

Complaint

Exhibit G

1 OFFICIAL TRANSCRIPT PROCEEDING
2 FEDERAL TRADE COMMISSION
3
4
5
6 MATTER NO. 1423132
7
8
9 TITLE CARROT NEUROTECHNOLOGY, INC.
10 (ULTIMEYES)
11
12
13 DATE RECORDED: FEBRUARY 23, 2014
14
15 TRANSCRIBED: OCTOBER 28, 2014
16
17
18 PAGES 1 THROUGH 8
19
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23
24 BRAIN TRAINING MAKES BETTER BATTERS
25 YOUTUBE VIDEO

Complaint

1 FEDERAL TRADE COMMISSION

2 I N D E X

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4 RECORDING: PAGE:

5 Brain Training Makes Better Batters 4

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FEDERAL TRADE COMMISSION

In the Matter of:)
Carrot Neurotechnology, Inc.,) Matter No. 1423132
(Ultimeyes))
-----)

February 23, 2014

The following transcript was produced from a
digital file provided to For The Record, Inc. on October
22, 2014.

Complaint

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1 P R O C E E D I N G S
2 - - - - -
3 BRAIN TRAINING MAKES BETTER BATTERS - YOUTUBE VIDEO
4 ON SCREEN: University of California
5 UC RIVERSIDE
6 www.ucr.edu
7 ON SCREEN: AARON SEITZ
8 Associate Professor, Psychology
9 AARON SEITZ: There are, you know, over 100
10 million people worldwide who have serious vision problems
11 that impact their lives. And, so, if we could use brain
12 training to improve their vision, this has profound
13 benefit to their lives. I decided that I wanted to try
14 to create something which would have real-world impact.
15 ON SCREEN: DOUG SMITH
16 Head Coach, UCR Baseball
17 DOUG SMITH: In Major League Baseball, the
18 vision training has really become a prevalent thing.
19 ON SCREEN: JENNI DEVEAU
20 Postdoctoral Researcher, Psychology
21 JENNI DEVEAU: We did a study with the 2013 UCR
22 baseball team where we did vision assessments before
23 their season started and then we conducted training.
24 They came in to our lab. Because they are already
25 started off with really good vision, we had to really

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1 challenge their vision.

2 After the season was over, we had tons of
3 baseball data and searched for the help of Dan Ozer to
4 let us know what does all this mean, what can we do with
5 all this.

6 ON SCREEN: DANIEL OZER

7 Professor, Psychology

8 DANIEL OZER: I was able to look at the
9 improvement of the players in terms of more hits, more
10 base on balls, additional bases, and I put that
11 information into a formula that was developed about
12 thirty years ago by a man named Bill James whose methods
13 have become famous in the book Moneyball and was able to
14 see how many runs were created in addition to what you
15 would expect if there had just been normal improvement.

16 AARON SEITZ: With Dan Ozer, we had discussed
17 that, you know, if they won one extra game based upon
18 this calculation, this would be huge.

19 DANIEL OZER: And then I placed that into the
20 context of how many runs the UCR pitchers allowed and
21 came up with this estimate of it made a difference of
22 somewhere between four and five games. I was shocked.
23 There has been a lot of interest in the last couple of
24 decades, people with a very serious interest in
25 statistics beginning to look at baseball data because

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1 it's runs and runs allowed that win and lose games.

2 DOUG SMITH: From an offensive standpoint, I
3 think our strike zone judgment has got better. Any time
4 we can get in that situation, our on-base percentage is
5 going to go up, all because we have the ability to lay
6 off a pitch because we see it just a little bit more
7 clearly.

8 JENNI DEVEAU: Many of the players, they
9 described being able to see things in dimmer light
10 conditions, being able to see the ball better, being able
11 to hit the ball better. They had less strikeouts
12 compared to the rest of the league and they had more runs
13 created.

14 DOUG SMITH: In our game, the margin of error
15 is so small that any edge we get can take us over the
16 top.

17 ON SCREEN: 31% IMPROVEMENT IN VISION
18 4.4% FEWER STRIKEOUTS
19 41 MORE RUNS
20 4 TO 5 MORE WINS

21 AARON SEITZ: The key idea is that you're not
22 changing how the eyes were; you're making the brain more
23 efficient at processing the information from the eyes.

24 DANIEL OZER: It made a difference of somewhere
25 between four and five games, and there will be lots of

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1 baseball players interested in getting this training.

2 AARON SEITZ: What I've been able to do is take
3 my research that started looking at a very simple basic
4 science problem and turn it into a game that anybody
5 could play that has real-world benefits.

6 ON SCREEN: For more information

7 UCRTODAY.UCR.EDU

8 (The video recording was concluded.)

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1 C E R T I F I C A T I O N O F T Y P I S T

2

3 MATTER NUMBER: 1423132

4 CASE TITLE: CARROT NEUROTECHNOLOGY, INC. (ULTIMEYES)

5 TAPING DATE: FEBRUARY 23, 2014

6 TRANSCRIPTION DATE: OCTOBER 28, 2014

7

8 I HEREBY CERTIFY that the transcript contained
9 herein is a full and accurate transcript of the tapes
10 transcribed by me on the above cause before the FEDERAL
11 TRADE COMMISSION to the best of my knowledge and belief.

12

13 DATED: OCTOBER 28, 2014

14

15

16 ELIZABETH M. FARRELL

17

18 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

19

20 I HEREBY CERTIFY that I proofread the transcript for
21 accuracy in spelling, hyphenation, punctuation and
22 format.

23

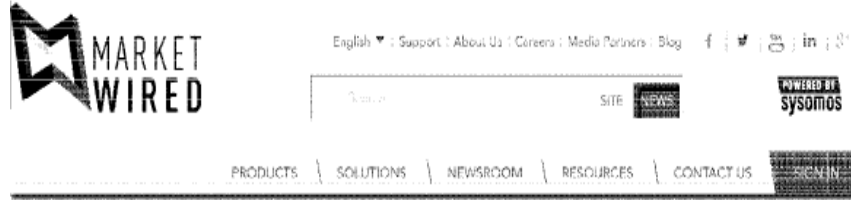
24

25 SARA J. VANCE

Exh. G

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Exhibit H



ULTIMEYES



April 18, 2014 09:00 ET

Chart-Topping ULTIMEYES® App Now Available for iPhone and Android Devices

App Scientifically Shown to Improve Vision is Downloadable Now in the Apple App Store for the iPad and iPhone, and Android Phones via Google Play and Amazon's Appstore for Android

LOS ANGELES, CA--(Marketwired - April 18, 2014) - Carrot Neurotechnology, Inc. announced today that its popular vision-enhancing interactive game App, ULTIMEYES®, has launched for all iOS and Android platforms. Previously available only for the PC, Mac and iPad, anyone with an iPhone or Android device can now improve their vision...at home or on the go. Improve the clarity of your vision and ability to see in poor lighting, lessen the need for reading glasses, and improve vision for sports and other everyday activities for a better lifestyle. From athletes who want to sharpen their "perfect vision" to people who struggle with low vision issues, ULTIMEYES® has been scientifically shown to help increase vision capabilities via perceptual learning.

"We are excited to bring the ULTIMEYES® App to mobile users around the world. We have received an enormous amount of positive feedback from users who are experiencing better vision, with some noticing improvement in as little as three weeks," said Adam Goldberg, CEO of Carrot Neurotechnology, Inc. "We want everyone with access to a PC/Mac, Android and Apple device to be able to benefit from this easy-to-use app that works as a competitive and fun game."

"Having worked with professional teams and individual athletes on vision training for the past 41 years, I'm always looking for new tools to add to my regimen when trying to give the pros an edge," said Dr. Bill Harrison, O.D. of SlowTheGameDown in Laguna Beach, CA. "When I heard about the results that the UC Riverside baseball program had with ULTIMEYES, we reviewed it and decided to add it to our sports vision program."

The most notable study¹ was conducted by the University of California, Riverside in collaboration with the UCR Highlanders baseball team. On average, the visual acuity increased 31%, with seven of the players' vision improving to 20/7.5 using a standard Snellen chart. Normal vision using the Snellen chart is 20/20. The improved vision resulted in batting performance strikeouts decreasing 4.4% and increasing the number of runs created. Using Bill James² formula for runs created, the researchers calculated that the team created 41 more runs, resulting in 4 to 5 additional wins for the season. Looking at other standard measures of offensive performance (Batting Average, Slugging Percentage, On Base Percentage, Walks, and Strike Outs), in every case UCR's year-over-year improvements were substantially greater (at least 3X) than the rest of the league.

ULTIMEYES® is an easy-to-use integrated app that uses a series of special game-like exercises that

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stimulate brain plasticity to make visual processing more efficient. Brain plasticity is the brain's mechanism that allows us to acquire new skills or improve upon the ones we already have, including vision. The program should be used four times per week for eight weeks, and each session is only 25 minutes long. Though results vary from person to person, on average, ULTIMEYES® users that have participated in ULTIMEYES studies could read one or two lines better on the Snellen eye chart and experienced a 100% increase in contrast sensitivity. Studies have been conducted with high performance athletes, law enforcement agencies, and people of all ages, genders and vision capabilities. Additional studies looking at other vision-related issues and applications are already underway. For more information on ULTIMEYES® please visit www.ultimeyesvision.com and www.youtube.com/ultimeyes.

About Carrot Neurotechnology, Inc.

Carrot Neurotechnology, Inc. is a private company founded by neuroscientists and video-game professionals, and is focused on developing new perceptual learning mechanisms that deliver improved vision and an enhanced lifestyle. Carrot Neurotechnology, Inc. develops and sells its patent pending integrated game program, ULTIMEYES®, that delivers affordable, safe, and comprehensive vision improvement for sports, reading, driving, and relieving the need for traditional visual aids used for age related eye conditions such as presbyopia and loss of contrast sensitivity.

¹ The study was published by the peer-reviewed journal, Current Biology - February, 2014.

² Bill James' methods for baseball statistics and analysis were made famous in the movie Moneyball.

<http://www.amazon.com/ULTIMEYES>

<https://play.google.com/ULTIMEYES>

<http://appstore.com/ULTIMEYES>

www.ultimeyesvision.com

CONTACT INFORMATION

Ryh-Ming Poon
PR@ultimeyesvision.com



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Exhibit I



University of California Reports Findings That ULTIMEYES® Produces Better Vision and Real World Benefits – Published in Current Biology

A study conducted with UCR Baseball Team demonstrates that Carrot Neurotechnology Inc.'s interactive vision training game ULTIMEYES® produces improved vision and quantifiable real world benefits.

Calabasas, CA (PRWEB) February 17, 2014

Carrot Neurotechnology, Inc. today announced that the peer-reviewed journal Current Biology published the results of a study entitled "Improved vision and on-field performance in baseball through perceptual learning," in the February 17th issue, which demonstrates that improved vision resulting from Carrot Neurotechnology's integrated interactive game program ULTIMEYES® yields improved vision with real world benefits. In this peer-reviewed journal, the researchers go on to say that the results of the study demonstrate the ability to deliver real world benefits across a broad range of activities ranging from athletics to more routine lifestyle activities such as reading, watching TV and driving.

The study was conducted by the University of California Riverside and the University of California Riverside baseball team prior to the 2013 season and included 37 players. As a result of using the integrated interactive game program visual acuity of the trained players increased 31% following use of the program and 7 of the players reached impressive 20/7.5 Snellen acuity. Contrast sensitivity function improved similarly in the trained players. Baseball players typically have excellent vision, so the extent of the improvement surprised the researchers. Players reported, "My eyes feel stronger", "I can see the ball better while I'm hitting", "I have greater peripheral vision. Easy to see further", "I can tell a change in dim light and being able to distinguish lower contrasting things."

Acuity is the sharpness of vision and contrast sensitivity is the ability to see details in low contrast such as seeing in dim light at night.

Testing ULTIMEYES® in baseball players enabled analysis of real world performance, in this case batting performance. The study demonstrated that trained players delivered better on-field performance than before use of the program including 4.4% fewer strikeouts, generated 41 more runs to achieve 4 to 5 more wins. UCR's year-over-year improvements were at least three times greater than the rest of the league in batting average, slugging percentage, on-base percentage, walks and strikeouts, the researchers determined.

UCR's Head Baseball Coach Doug Smith said, "I didn't think we would see as much of an improvement as we did. Our guys stopped swinging at some pitches and started hitting at others. Their average strikeout total went down and batting went up."

"This study reaffirms that our product delivers improved visual performance and confirms that these improvement transfer into practical real-world benefits. We're encouraged and excited by the broad range of lifestyle benefits that many individuals who rely on vision including athletes but also those with normal vision and low vision going about their routine tasks," said Adam Goldberg, CEO of Carrot Neurotechnology, Inc.

The publication is available now at: <http://www.cell.com/current-biology/>

Video summary available at: <http://youtu.be/EKbbF86cyqI>.

ULTIMEYES® is currently available for Microsoft Windows, Mac OS X and iPad and will soon be available on Android tablets. For more information about ULTIMEYES®, visit ultimeyesvision.com.

About Carrot Neurotechnology, Inc.

Carrot Neurotechnology, Inc. is a private company founded by cognitive neuroscientists, vision scientists, and former video-game executives focused on developing new perceptual learning mechanisms that deliver improved vision and enhanced lifestyle. Carrot Neurotechnology, Inc. develops and sells its patent pending integrated game program ULTIMEYES® that delivers affordable safe comprehensive vision improvement for sports, reading, driving and relieving need for traditional visual aids used for age-related eye conditions such as presbyopia and loss of contrast sensitivity.

About Current Biology

Cell Press is committed to improving scientific communication through the publication of exciting research and reviews. As we introduce publications and expand our online content to serve our growing audience, our mission remains to publish and develop journals that deliver the highest possible intellectual rigor, promote community trust, and are widely disseminated. Cell Press primary research journals include the flagship journal Cell. For more information, please visit <http://www.cell.com>.

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Complaint

About University of California, Riverside

The University of California, Riverside (<http://www.ucr.edu>) is a doctoral research university, a living laboratory for groundbreaking exploration of issues critical to Inland Southern California, the state and communities around the world. Reflecting California's diverse culture, UCR's enrollment has exceeded 21,000 students. The campus opened a medical school in 2013 and has reached the heart of the Coachella Valley by way of the UCR Palm Desert Center. The campus has an annual statewide economic impact of more than \$1 billion. A broadcast studio with fiber cable to the AT&T Hollywood hub is available for live or taped interviews. UCR also has ISDN for radio interviews. To learn more, call (951) UCR-NEWS.

Contact Information

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+1 310 210-4338

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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 attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”) that includes: a statement that the respondents neither admit nor deny any of the allegations in the draft complaint except as specifically stated in the consent agreement; an admission by the respondents of facts necessary to establish jurisdiction for purposes of this action; 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 the respondents have violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of 30 days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Carrot Neurotechnology, Inc. (“Carrot”) is a California corporation with its principal office or place of business at 3995 Prado De Las Frutas, Calabasas, California, 91302.
2. Respondent Adam Goldberg is an owner and officer of Carrot. Individually or in concert with others, he

Decision and Order

formulates, directs, or controls the policies, acts, and practices of the corporation.

3. Respondent Aaron Seitz is an owner and officer of Carrot. Individually or in concert with others, he formulates, directs, or controls the policies, acts, and practices of the corporation.
4. The 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:

- A. Unless otherwise specified, “Respondents” shall mean Carrot Neurotechnology, Inc., a corporation, its successors and assigns and its officers; Adam Goldberg, individually and as an officer of the corporation; Aaron Seitz, individually and as an officer of the corporation; and each of the above’s agents, representatives, and employees.
- B. “Clearly and conspicuously” shall mean that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the

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communication even if the representation requiring the disclosure is made through only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
5. On a product label, the disclosure must be presented on the principal display panel.
6. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
7. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
8. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
9. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, “ordinary consumers” includes reasonable members of that group.

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- C. “Close proximity” shall mean that the disclosure is very near the triggering representation. In an interactive electronic medium (such as a mobile app or other computer program), a visual disclosure that cannot be viewed at the same time and in the same viewable area as the triggering representation, on the technology used by ordinary consumers, is not in close proximity. A disclosure made through a hyperlink, pop-up, interstitial, or other similar technique is not in close proximity to the triggering representation. A disclosure made on a different printed page than the triggering representation is not in close proximity.
- D. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- E. “Covered Product or Service” shall mean any Device, as defined below, or any program or service that is:
1. intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals; and
 2. which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
- F. “Device” shall mean, as defined in Section 15 of the FTC Act, 15 U.S.C. § 55, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;

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2. intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
3. intended to affect the structure or any function of the body of man or other animals; and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

- G. “Endorsement” shall mean, as defined in 16 C.F.R. § 255.0(b), any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group, or institution.
- H. “Material connection” shall mean any relationship that materially affects the weight or credibility of any endorsement and that would not be reasonably expected by consumers.
- I. “Person” shall mean a natural person, an organization, or another legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.
- J. “Reliably Reported,” for a human clinical test or study (“test”), shall mean a report of the test has been published in a peer-reviewed journal, and such

Decision and Order

published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

- K. The term “including” in this order shall mean “including without limitation.”
- L. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, including, but not limited to, Ultimeyes, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a name, endorsement, depiction, or illustration, that the Covered Product or Service improves users’ vision, including that the Covered Product or Service:

- A. Improves the vision of users, including people of all ages, genders, and visual abilities;
- B. Improves vision with real world benefits, including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving;
- C. Improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and
- D. Reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users’ ability to read in dim light,

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and diminishing the need for glasses or other visual aids,

unless the representation is non-misleading and, at the time of making such representation, Respondents possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product or Service that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall (1) be randomized, double-blind, and adequately controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of such testing as set forth in Part III must be available for inspection and production to the Commission.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a name, endorsement, depiction, or illustration, any representation, other than representations covered under Part I of this order, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or Service, unless the representation is non-misleading, and, at the time of making such representation, Respondents possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses,

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research, or studies (A) that have been conducted and evaluated in an objective manner by qualified persons; (B) that are generally accepted in the profession to yield accurate and reliable results; and (C) when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in Part III are available for inspection and production to the Commission.

III.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study (“test”) upon which Respondents rely to substantiate any claim covered by Parts I or II of this order, Respondents shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including, but not necessarily limited to:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including, but not limited to,

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any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

- E. All documents referring or relating to the sponsorship of the test, including all contracts and communications between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by Respondents, or by any person or entity affiliated with or acting on behalf of Respondents, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with Respondents, or (2) by Respondents' programmers, manufacturers, or suppliers of any component of the Covered Product or Service.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures shall be documented in writing and 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 the participants.

IV.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, program, or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a name, endorsement, depiction, or illustration:

- A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or

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- B. That any benefits of such product, program, or service are scientifically proven.

V.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, program, or service in or affecting commerce, shall disclose, clearly and conspicuously, and in close proximity to the triggering representation:

- A. For any representation that any test, study, or research supports any claims about the product, program, or service, all material connections with any person that has conducted, authored, or participated in the test, study, or research; and
- B. For any endorsement of such product, program, or service, all material connections between the person providing the endorsement and Respondents or any other person manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, program, or service.

VI.

IT IS FURTHER ORDERED that:

- A. Respondents shall pay to the Commission \$150,000, which Respondents have stipulated their undersigned counsel holds in escrow for no purpose other than payment to the Commission.
- B. Such payment shall be made within 8 days of the effective date of this order by electronic funds transfer in accordance with instructions provided by a representative of the Commission.

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- C. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this order and may not seek the return of any assets.
- D. The facts alleged in the complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this order, such as a nondischargeability complaint in any bankruptcy case.
- E. The facts alleged in the complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this order will have collateral estoppel effect for such purposes.
- F. All money paid to the Commission pursuant to this order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Part.
- G. In the event of default on any obligation to make payment under this order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that

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payment is due, the entire amount will immediately become due and payable.

- H. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.
- I. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this order, in accordance with 31 U.S.C. § 7701.

VII.

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress to all purchasers of Ultimeyes. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

VIII.

IT IS FURTHER ORDERED that Respondent Carrot Neurotechnology, Inc. and its successors and assigns, and Respondents Adam Goldberg and Aaron Seitz shall, for 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;

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- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its 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; and
- D. All acknowledgements of receipt of this order obtained pursuant to Part IX.

IX.

IT IS FURTHER ORDERED that Respondent Carrot Neurotechnology, Inc. and its successors and assigns, and Respondents Adam Goldberg and Aaron Seitz 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 30 days after the date of service of this order, and to future personnel within 30 days after the person assumes such position or responsibilities.

X.

IT IS FURTHER ORDERED that Respondent Carrot Neurotechnology, Inc. and its successors and assigns, and Respondents Adam Goldberg and Aaron Seitz shall notify the Commission at least 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;

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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 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. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580. The subject line must begin: *In re Carrot Neurotechnology, Inc.*

XI.

IT IS FURTHER ORDERED that Respondent Carrot Neurotechnology, Inc. and its successors and assigns, and Respondents Adam Goldberg and Aaron Seitz, within 60 days after the date of service of this order, each shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within 10 days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, these reports shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580. The subject line must begin: *In re Carrot Neurotechnology, Inc.*

XII.

This order will terminate on February 22, 2036, or 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:

Analysis to Aid Public Comment

- A. Any Part in this order that terminates in less than 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.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order as to Carrot Neurotechnology, Inc., Adam Goldberg, and Aaron Seitz (hereafter "respondents").

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

Analysis to Aid Public Comment

This matter involves the respondents' advertising for the Ultimeyes software application. The Commission's complaint alleges that the respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a), 52, by representing, either falsely or without adequate substantiation, that Ultimeyes substantially improves users' vision, including that it: improves the vision of users, including people of all ages, genders, and visual abilities; improves vision with real world benefits, including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving; improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light, and diminishing the need for glasses or other visual aids. The complaint also alleges that the respondents violated Sections 5(a) and 12 by making the false or misleading representation that scientific testing proves that Ultimeyes improves vision in the above ways.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The order applies to marketing claims for any Covered Product or Service, defined as any Device within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. §§ 52, 55, or any program or service that is: (1) intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (2) intended to affect the structure or any function of the body of man or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. As additional fencing-in relief, the order requires the respondents to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that it conducts or sponsors on any Covered Product or Service.

Analysis to Aid Public Comment

Part I prohibits any representation that a Covered Product or Service improves users' vision, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing of the Covered Product or Service that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall (1) be randomized, double-blind, and adequately controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, the respondents must maintain all underlying or supporting data that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part II prohibits any representation about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or Service, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons; and that are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of human clinical tests or studies, the respondents must maintain all underlying or supporting data and documents that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part III, triggered when the human clinical testing requirement in Parts I or II applies, requires the respondents to secure and preserve all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test that is published in a peer-reviewed journal and that was not conducted, controlled, or

Analysis to Aid Public Comment

sponsored by any respondent or by any supplier of the respondents. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part IV prohibits the respondents from misrepresenting, including through the use of a name, endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or that any benefits of a product, program, or service are scientifically proven.

Part V requires the respondents to disclose, when triggered by certain representations as to scientific support or endorsements in connection with the advertisement or sale of any product, program, or service, any material connections to any person that has conducted, authored, or participated in any test, study, or research of the product, program, or service; and all material connections between a person providing an endorsement and respondents or any other person manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, program, or service.

Part VI provides the respondents will pay an equitable monetary payment of \$150,000 and contains other provisions related to the payment.

Part VII requires the respondents to provide sufficient customer information to administer redress.

Part VIII contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III, as well as order acknowledgments covered by Part IX.

Parts IX through XI require the respondents to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Concurring Statement

Part XII provides that, with exceptions, the order will terminate in twenty years.

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

**Concurring Statement of Commissioner Maureen K.
Ohlhausen**

On September 17, 2015, the Commission issued an administrative complaint and accepted a proposed administrative consent agreement with Carrot Neurotechnology, Inc., regarding allegedly false and unsubstantiated vision improvement claims for Ultimeyes, a video game app.¹ The Commission subsequently published a description of the consent agreement package in the Federal Register, seeking public comment.² The Commission received seventy-seven comments, including many from experts and researchers in the relevant field of perceptual learning.

The Commission now votes to issue the consent agreement without modification and to address commenter concerns in a responsive letter. I concur, but write separately to emphasize our response to one particular set of concerns raised by commenters.

1 In the Matter of Carrot Neurotechnology, Inc., FTC File No. 1423132 (Sept. 17, 2015).

2 Carrot Neurotechnology, Inc., Analysis of Proposed Consent Order To Aid Public Comment, 80 Fed. Reg. 57614 (Sept. 24, 2015), <https://www.federalregister.gov/articles/2015/09/24/2015-24220/carrot-neuro-technology-inc-analysis-of-proposed-consent-order-to-aid-public-comment#h-4>. All public comments on this matter are available at <https://www.ftc.gov/policy/public-comments/initiative-625>.

Concurring Statement

Part I of the consent agreement requires that Carrot substantiate any future vision improvement claims through testing that is “double-blinded.”³ Many commenters expressed concern about this blinding requirement.⁴ For example, one commenter explained that “[i]n perceptual experiments it is impossible to produce an intervention to which the participant is ‘blinded’ in the way that a pill or a cream can appear to be identical regardless of whether or not the active ingredient is present.”⁵ Another noted that it is difficult to control for a test subject’s expectations “for learning from behavioral training techniques where a person is actively engaged with learning materials that they are aware of.”⁶ Still another argued that so-called “placebo” effects are mental changes that are relevant to perceptual and cognitive learning.⁷

These are legitimate concerns about the apparent rigidity of the agreement’s blinding requirement.⁸ However, the blinding requirement already is context-sensitive and flexible – more so than the commenters may realize. As our letter to commenters properly explains, the blinding requirement is flexible because

3 Consent Agreement at 5.

4 *See, e.g.*, Comments of Russell Cohen Hoffing (Sept. 17, 2015); Comments of Tony Simon (Sept. 17, 2015); Comments of C. Shawn Green (Sept. 17, 2015); Comments of Esther Gonzalez (Oct. 8, 2015); Comments of Daphne Bavelier (Oct. 14, 2015).

5 Comments of Frederick Gallun (Oct. 4, 2015). *See also* Comments of Daniel Polley (Oct. 17, 2015); Comments of Kyrstel R. Huxlin, PhD, at 1 (Oct. 2, 2015); Comments of Lori Holt (Oct. 5, 2015); Comments of Krish Sathian (Oct. 19, 2015).

6 Comments of Whyte (Sept. 21, 2015).

7 Comments of Stanley Klien (Oct. 18, 2015). *See also* Comments of Hans Strasburger (Oct. 6, 2015).

8 Indeed, the D.C. Circuit has found that “rigid remedial rules” could deny consumers “useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease.” *POM Wonderful, LLC, v. FTC*, 777 F.3d 478, 502-03 (D.C. Cir. 2015). In that case, the court upheld a substantiation standard that required double-blinding “whenever feasible.” *Id.* at 500-503.

Concurring Statement

“[w]hat constitutes appropriate blinding and controls ... may differ depending on the nature of the intervention and other circumstances.”⁹ The letter also provides examples of practices that may constitute adequate blinding in this context.

It might be more straightforward if the agreement itself explained the blinding requirement’s flexibility. However, I believe our letter to commenters adequately explains the Commission’s position on double-blinding in this case. Therefore, I concur.

⁹ Letter at 3.

Complaint

IN THE MATTER OF

MACHINIMA, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4569; File No. 142 3090*
Complaint, March 16, 2016 – Decision, March 16, 2016

This consent order addresses Machinima, Inc.'s failure to make appropriate disclosures about content relating to video games and gaming culture via a multi-channel network on YouTube.com. The complaint alleges that Respondent's influencers did not disclose that Respondent offered compensation to the influencers in exchange for creating and uploading the videos as part of the advertising campaign. The complaint further alleges that Respondent's influencers' videos did not reflect the independent opinions of impartial video game enthusiasts. The consent order requires Respondent to clearly and prominently disclose in any Influencer Campaign a material connection, if one exists, between the Endorser and the advertiser whose product is being endorsed.

Participants

For the *Commission*: Julie Mayer, Richard McKewen, and Connor Shively.

For the *Respondent*: Linda Goldstein, Manatt, Phelps & Phillips, LLP.

COMPLAINT

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

1. Respondent is a Delaware corporation with its principal office or place of business at 8441 Santa Monica Blvd, West Hollywood, CA 90069.

Complaint

2. The acts and practices of Respondent, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

3. Respondent is a video entertainment company that produces and distributes content relating to video games and gaming culture via a multi-channel network (“MCN”) on YouTube.com. Respondent’s network features original content such as scripted and non-scripted series, official content from video game publishers and developers, and game-play videos produced by individual gamers.

4. Respondent’s MCN is one of the top entertainment networks on YouTube, generating more than 3 billion views each month and reaching over 407 million subscribers.

5. Respondent generates revenue by selling advertising on its network. The advertising offered by Respondent includes video ads that appear prior to or in the middle of selected content, display ads, and other advertising formats available on YouTube.

6. In late 2013, Microsoft Corporation released its Xbox One gaming platform and published three companion video games — *Forza 5*, *Dead Rising 3*, and *Ryse: Son of Rome* (“Launch Titles”). In the months leading up to the release, Microsoft, through its advertising agency Starcom MediaVest Group, Inc. (“Starcom”), embarked on a global advertising campaign to promote the Xbox One and the new Launch Titles.

7. In mid-2013, Respondent submitted a proposal to Starcom and Microsoft to market the Xbox One and the Launch Titles on Respondent’s YouTube network. In addition to proposing traditional display, pre-roll, and other advertising, Respondent proposed leveraging a group of “influencers” that Respondent could “incentivize . . . to create content” on YouTube. These influencers would make and upload their own game-play videos and “generate millions of organic views around the Xbox One platform and launch titles” and “build early buzz” surrounding the new platform and games.

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8. Respondent eventually entered into a written agreement with Starcom to provide advertising on behalf of Microsoft as outlined in Respondent's proposal. Under the terms of the agreement, Respondent committed to engage its influencers to create videos promoting the Xbox One and the Launch Titles. Respondent promised that the influencer videos would "not portray [Microsoft], the Xbox One, or the Launch Titles in a negative manner," and Microsoft could request that Respondent take down any video that violated this promise. Respondent guaranteed that the influencer videos would be viewed a minimum of 19,000,000 times.

PHASE ONE OF RESPONDENT'S INFLUENCER PROGRAM

9. In Phase One of Respondent's influencer program, Respondent recruited five of its influencers to produce and upload two video reviews each. The statement of work given to each influencer provided explicit instructions as to the content of each video.

10. Respondent directed each influencer to include in their first video review:

- *Montage of past Xbox 360 footage, talking over a game you're playing on the Xbox 360, etc.*
- *Two to three talking points detailing what features you're looking forward to in the Xbox One*
- *Announce that you will be playing Ryse on the Xbox early*
- *Video will be at least 2 minutes long in length*
- *Video showcases Microsoft products in positive light*

Respondent directed each influencer to include in their second video review:

- *Capture Ryse gameplay in Machinima office*
- *Two to three talking points detailing what you like about the game*
- *Video will be at least 2 minutes long in length*
- *Video showcases Microsoft in positive light*

Complaint

Respondent provided separately the talking points to be covered in each video.

11. According to the statement of work, the videos produced by the five influencers were Respondent's property, "work-made-for-hire with Machinima as sole owner of all rights, title, and interest, including any and all copyright therein, worldwide, in perpetuity." Pursuant to a separate promotion agreement with Respondent applicable to all of Respondent's campaigns, the influencers "agree[d] to keep confidential at all times in perpetuity all matters relating to" their agreement with Respondent.

12. The five influencers were required to create and upload the videos to YouTube before the Xbox One and Launch Titles were available to the general public. To facilitate the creation of the videos, Microsoft provided Respondent with pre-release versions of *Ryse* and the Xbox One console, and Respondent made them available to its influencers.

13. In November 2013, each of the influencers uploaded to their individual YouTube channels the two videos ordered by Respondent. Respondent, Starcom, and Microsoft reviewed and approved each of the videos. Respondent compensated each influencer in accordance with the influencer's statement of work with Respondent.

14. Neither the statements of work nor the master promotion agreement with the influencers required the influencers to disclose in their videos that they had been compensated. Respondent did not otherwise oblige the influencers to disclose in their videos that they had been compensated.

15. Respondent paid influencer Adam Dahlberg \$15,000 for the two video reviews that he uploaded to his YouTube channel "SkyVSGaming." In his videos, Dahlberg speaks favorably of Microsoft, Xbox One, and *Ryse*. Dahlberg's videos appear to be independently produced and give the impression that they reflect his personal views. Nowhere in the videos or in the videos' descriptions did Dahlberg disclose that Respondent paid him to create and upload them. Dahlberg's first video received more

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than 360,000 views, and his second video more than 250,000 views.

16. Respondent paid influencer Tom Cassell \$30,000 for the two video reviews that he uploaded to his YouTube channel “TheSyndicateProject.” In his videos, Cassell speaks favorably of Microsoft, Xbox One, and *Ryse*. Cassell’s videos appear to be independently produced and give the impression that they reflect his personal views. Nowhere in the videos or in the videos’ descriptions did Cassell disclose that Respondent paid him to create and upload them. Cassell’s first video received more than 730,000 views, and his second video more than 300,000 views.

PHASE TWO OF RESPONDENT’S INFLUENCER PROGRAM

17. In Phase Two of the influencer program, Respondent recruited members of its entire network of influencers to produce and upload videos. Respondent promised to pay each influencer \$1.00 for every 1,000 views of an influencer’s video, up to an aggregate cap of \$25,000 for the entire campaign. Phase Two was open to any influencer willing to sign a Video Campaign Agreement (“VCA”).

18. The VCA imposed several conditions that had to be met before an influencer could be paid for producing and uploading a video. Among other things,

- The influencer’s video had to be at least 60 seconds long and include at least 30 seconds of gameplay or other footage from any combination of the Xbox One and the Launch Titles within the first two minutes of the video.
- The video could not contain anything negative or disparaging regarding Machinima, Xbox One, or any Launch Title.
- The video had to provide a link to either the Xbox One YouTube Channel or another qualifying video on the influencer’s YouTube channel.

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- The video had to be uploaded to the influencer's YouTube channel and tagged with the "XB1M13" tag.

19. The VCA included a confidentiality provision requiring the influencer to "keep confidential at all times all matters relating to [the] Agreement," which included the conditions listed in the previous paragraph and the influencer's compensation.

20. The VCA did not require Respondent's influencers to disclose that Respondent had offered compensation in exchange for creating and uploading the video.

21. Respondent's influencers produced and uploaded to YouTube over 300 videos that, between November 22 and December 31, 2013, generated more than 30 million views. In many of the videos, influencers spoke favorably of Microsoft, Xbox One, and the Launch Titles, and the influencers gave the impression that their videos were independently produced and that their comments reflected the influencer's personal views. In numerous instances, nowhere in the videos or in the videos' descriptions did the influencers disclose that Respondent had offered compensation in exchange for creating and uploading the video.

22. At the conclusion of the campaign, Respondent compensated the influencers for their videos in accordance with the VCA, up to the \$25,000 aggregate cap.

VIOLATIONS OF THE FEDERAL TRADE COMMISSION ACT

23. Through the means described in Paragraphs 9 through 22, Respondent has represented, directly or indirectly, expressly or by implication, that video reviews of Microsoft's Xbox One and the Launch Titles reflected the independent opinions of impartial video game enthusiasts.

24. In truth and in fact, the video reviews for Xbox One and the Launch Titles did not reflect the independent opinions of impartial video game enthusiasts. Respondent's influencers created the video reviews as part of the global advertising

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campaign to promote sales of Xbox One and the Launch Titles. Therefore, the representation set forth in Paragraph 23 was, and is, false and misleading.

25. Through the means described in Paragraphs 9 through 22, Respondent has represented, directly or indirectly, expressly or by implication, that favorable video reviews for Xbox One and the Launch Titles were posted online by individuals who had played Xbox One or the Launch Titles. In numerous instances, Respondent has failed to disclose, or disclose adequately, that the individuals who posted the reviews were compensated in connection with their endorsements. This fact would be material to consumers in their purchasing decisions regarding Xbox One and the Launch Titles. The failure to disclose this fact, in light of the representations made, was, and is, a deceptive practice.

26. The acts and practices of Respondent 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 sixteenth day of March, 2016, has issued this Complaint against Respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“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 complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the

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Commission, would charge the Respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 et seq.; and

The Respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), which includes a statement by the Respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the consent agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; 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 the Respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Machinima, Inc. (“Machinima”), is a Delaware corporation with its principal office or place of business at 8441 Santa Monica Blvd, West Hollywood, CA 90069.
2. The Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

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

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- A. Unless otherwise specified, “Respondent” shall mean Machinima, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- C. “Clearly and prominently” shall mean as follows:
1. In textual communications (e.g., printed publications or words displayed on the screen of a computer), the required disclosures are of a type, size, and location sufficiently noticeable for an ordinary consumer to read and comprehend them, in print that contrasts with the background on which they appear;
 2. In communications disseminated orally or through audible means (e.g., radio or streaming audio), the required disclosures are delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend them;
 3. In communications disseminated through video means (e.g., television or streaming video), the required disclosures are in writing in a form consistent with subparagraph (a) of this definition and shall appear on the screen for a duration sufficient for an ordinary consumer to read and comprehend them.
 4. In communications made through interactive media, such as the Internet, online services, and software, the required disclosures are unavoidable and presented in a form consistent with subparagraph (a) of this definition, in addition to any audio or video presentation of them; and
 5. In all instances, the required disclosures are presented in an understandable language and

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syntax, in the same language as the predominant language that is used in the communication, and with nothing contrary to, inconsistent with, or in mitigation of the disclosures used in any communication of them.

- D. “Endorsement” means any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness, or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.
- E. “Endorser” means an individual or organization that provides an Endorsement.
- F. “Influencer Campaign” means any arrangement whereby, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product or service, Respondent engages an Endorser (also known as an Influencer) to create, publish, or otherwise disseminate an online Endorsement for which the Influencer is to receive compensation from Respondent, the advertiser for whom Respondent conducts the campaign, or anyone else acting on their behalf.
- G. “Material connection” means any relationship that materially affects the weight or credibility of any endorsement and that would not be reasonably expected by consumers.
- H. The term “including” in this order means “without limitation.”

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I.

IT IS ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any product or service, in or affecting commerce, shall not in any Influencer Campaign misrepresent, in any manner, expressly or by implication, that an Endorser of such product is an independent user or ordinary consumer of the product or service.

II.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any product or service, in or affecting commerce, by means of an Endorsement of such product or service, shall in any Influencer Campaign clearly and prominently disclose a material connection, if one exists, between the Endorser and the advertiser whose product is being endorsed.

III.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any product or service, in or affecting commerce, shall take reasonable steps to ensure that its Influencer Campaigns comply with Parts I and II of this order. Such steps shall include, at a minimum:

- A. Establishing, implementing, and thereafter maintaining a system to monitor and review its Influencers' representations and disclosures to ensure compliance with Parts I and II of this order. As part of this system:
 1. Respondent shall provide each Influencer with a statement of his or her responsibility to disclose clearly and prominently, in any online video, social

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media posting, or other communication for which the Influencer is to receive compensation, the Influencer's material connection to the advertiser for whom Respondent is conducting the Influencer Campaign. The statement shall also inform the Influencer that Respondent will monitor for compliance. The statement may be included as part of any Influencer agreement, but the statement shall be on a separate page by itself, and written in a manner reasonably calculated to be easily understood by the Influencer. Respondent shall obtain from each Influencer a signed and dated acknowledgment that the Influencer has received the statement and expressly agrees to comply with it. Any electronic signature that Respondent obtains pursuant to this Part shall comply with the signature requirements of the Electronic Signatures in Global and National Commerce, 15 U.S.C. §§ 7001 *et seq.*

2. Prior to compensating any Influencer for an online video Endorsement, Respondent shall conduct an initial review of that Endorsement. If the video Endorsement fails to clearly and prominently disclose any material connection between the Influencer and the advertiser for whom Respondent is conducting the Influencer Campaign, then Respondent shall notify the Influencer of the failure to disclose, refrain from compensating the Influencer for the Campaign, and disqualify the Influencer from participating in future Influencer Campaigns until the video Endorsement contains the required disclosure. *Provided, however,* Respondent may compensate an Influencer in advance for an online video Endorsement if the video Endorsement is not uploaded to the Internet, publicly disseminated, or otherwise made publicly accessible until after Respondent has reviewed it and verified that it clearly and prominently discloses any material connection between the

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Influencer and the advertiser for whom Respondent is conducting the Influencer Campaign.

3. After an Influencer's video Endorsement has been uploaded to the Internet, publicly disseminated, or otherwise made publicly accessible, Respondent shall continue to monitor the online video Endorsement by conducting another review of it within ninety days of the date of the Influencer's final compensation, but not before two weeks after that date. The timing of this second review must not be disclosed in advance to the Influencer, and the manner of the review must be reasonably calculated not to disclose the source of the monitoring activity at the time it is being conducted. If the online video Endorsement is no longer publicly accessible nor reasonably accessible to Respondent at the time Respondent attempts the review required by this subparagraph 3, Respondent need not conduct the review of the online video.
4. If, after conducting the review described in the preceding subparagraph, or if at any other time subsequent to compensating an Influencer, Respondent reasonably concludes that the Influencer
 - a. has misrepresented, in any manner, the status of the Influencer, including but not limited to, the misrepresentation that such Influencer is an independent user or ordinary consumer; or
 - b. has failed to disclose, clearly and prominently, a material connection, when one exists, between such Influencer and the advertiser for whom Respondent is conducting the Influencer Campaign;

then Respondent shall immediately suspend the Influencer from, and withhold payments to the

Decision and Order

Influencer for, any Influencer Campaigns, until the Influencer cures such misrepresentation or discloses, clearly and prominently, such material connection. Respondent shall immediately terminate and disqualify the Influencer from future Influencer Campaigns upon a repeat incident;

- B. Creating, and thereafter maintaining, reports sufficient to show the results of the monitoring required by subpart A of this Part of the order.

IV.

IT IS FURTHER ORDERED that Respondent shall, for five (5) years after the last date of dissemination of any Endorsement or other representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying, any documents that:

- A. Are reasonably necessary to demonstrate full compliance with each provision of this order, including but not limited to, all documents obtained, created, generated, or which in any way relate to the requirements, provisions, terms of this order, and all reports submitted to the Commission pursuant to this order;
- B. Contradict, qualify, or call into questions Respondent's compliance with this order;
- C. Comprise or relate to complaints or inquiries, whether received directly, indirectly, or through any third party, concerning any endorsement made by Respondent, and any responses to those complaints or inquiries; and
- D. All acknowledgments of receipt of this order obtained pursuant Part V.

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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, 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. 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.

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 overnight courier (not the U.S. Postal Service) to the Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line: In the Matter of Machinima, Inc., FTC File Number 1423090. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of such notices is contemporaneously sent to the Commission at DEbrief@ftc.gov.

Decision and Order

VII.

IT IS FURTHER ORDERED that Respondent and its successors and assigns shall, within ninety (90) days after the date of service of this order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, Respondent shall submit additional true and accurate written reports.

VIII.

This order will terminate on March 16, 2036, 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 to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Machinima, Inc. (“Respondent”). 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 and take appropriate action or make final the agreement’s proposed order.

Respondent is a video entertainment company that produces and distributes content relating to video games and gaming culture via a multi-channel network (“MCN”) on YouTube.com. In 2013, Respondent was hired by Microsoft Corp. (“Microsoft”), through its advertising agency Starcom MediaVest Group (“Starcom”), to market the Xbox One gaming console and three companion video games (“Launch Titles”) on Respondent’s YouTube network. As part of Respondent’s advertising campaign for Microsoft, Respondent engaged and compensated its “influencers” (or “endorsers”) to create videos promoting the Xbox One and the Launch Titles. As part of its agreement with Starcom, Respondent promised that the influencer videos would “not portray [Microsoft], the Xbox One, or the Launch Titles in a negative manner,” and Microsoft could request that Respondent take down any video that violated this promise.

According to the complaint, in numerous instances, Respondent’s influencers did not disclose that Respondent offered compensation to the influencers in exchange for creating and uploading the videos as part of the advertising campaign. The FTC’s complaint alleges that Respondent’s influencers’ videos were false and misleading because they did not reflect the independent opinions of impartial video game enthusiasts. The complaint also alleges that these videos were deceptive because they failed to disclose the material fact that the influencers who posted the reviews were compensated in connection with their endorsements.

Analysis to Aid Public Comment

Part I of the proposed order prohibits Respondent from misrepresenting in any Influencer Campaign, that the Endorser is an independent user or ordinary consumer of the product or service. The proposed order defines an “Influencer Campaign” as any arrangement whereby, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product or service, Respondent engages an Endorser (also known as an Influencer) to create, publish, or otherwise disseminate an online Endorsement for which the Influencer is to receive compensation from either Respondent, the advertiser for whom Respondent conducts the campaign, or anyone else acting on their behalf.

Part II of the proposed order requires Respondent to clearly and prominently disclose in any Influencer Campaign a material connection, if one exists, between the Endorser and the advertiser whose product is being endorsed. The proposed order defines “material connection” as any relationship that material affects the weight or credibility of any endorsement and that would not be reasonably expected by consumers.

Part III of the proposed order requires Respondent to take reasonable steps to ensure that its Influencer Campaigns comply with Parts I and II. Respondent is required to provide each influencer with a plain language statement of his or her responsibility to disclose clearly and conspicuously any material connection to the advertiser on whose behalf Respondent is conducting the campaign, and Respondent must obtain a signed acknowledgment of receipt of this statement from the influencer. Respondent must also institute specific monitoring procedures for online video endorsements that are part of its Influencer Campaigns. Respondent may not compensate an influencer for a video endorsement that has been posted online or otherwise been made publicly available until Respondent verifies that the endorsement contains a clear and conspicuous disclosure about the influencer’s material connection to the advertiser. In addition, between two weeks and ninety days of compensating the influencer, Respondent must conduct another review of each video endorsement that is still publicly accessible or reasonably accessible to Respondent to ensure that any required disclosures remain.

Analysis to Aid Public Comment

Part IV of the proposed order contains recordkeeping requirements that, among other things, require Respondent to maintain records sufficient to demonstrate its compliance with Parts I through III of the order.

Parts V through VII of the proposed order require Respondents to: deliver a copy of the order to principals, officers, directors, managers, employees, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure, discontinuance of current business or employment, or affiliation with any new business or employment that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part VIII provides that the order will terminate after twenty (20) years, with certain exceptions.

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 complaint or proposed order or to modify the proposed order's terms in any way.

Complaint

IN THE MATTER OF

**RANGERS RENAL HOLDING, LP,
US RENAL CARE, INC.,
DIALYSIS PARENT, LLC,
AND
DIALYSIS HOLDCO, LLC.**

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

*Docket No. C-4570; File No. 151 0215
Complaint, March 17, 2016 – Decision, March 17, 2016*

This consent order addresses the \$640 million acquisition by Rangers Renal Holdings LP of certain assets of Dialysis Parent, LLC. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in Laredo, Texas, for the provision of outpatient dialysis services. Under the Order, US Renal Care, Inc. is required to divest Dialysis Newco, Inc.'s three dialysis clinics in Laredo, Texas.

Participants

For the *Commission*: Lisa D. DeMarchi Sleight, Sebastian Lorigo, Eric Rohlck, and Sarah Wohl.

For the *Respondents*: Amanda Reeves and Kory Wilmot, Latham & Watkins LLP; Gorav Jindal, Dechert LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that the Respondent Rangers Renal Holdings LP ("Rangers Holdings"), a company subject to the jurisdiction of the Commission, has entered into an agreement to acquire Dialysis Parent, LLC ("Dialysis Parent"), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45; that such acquisition, if consummated, would violate Section 7 of the of the Clayton Act,

Complaint

as amended, 15 U.S.C. § 18, and Section 5 of the 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. DEFINITIONS

1. “Dialysis” means the filtering of a person’s blood, inside or outside of the body, to replicate the functions of the kidney.

2. “ESRD” means end stage renal disease, a chronic disease characterized by a near total loss of function of the kidneys, which in healthy people remove toxins and excess fluid from the blood.

3. “Outpatient dialysis services” means all procedures and services related to administering chronic dialysis treatment.

II. RESPONDENTS

4. Respondent Rangers Holdings is a limited partnership 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 11111 Santa Monica Boulevard, Suite 2000, Los Angeles, CA 90025. Rangers Holdings is the parent of US Renal Care, Inc. (“USRC”), a Delaware corporation, with its office and principal place of business located at 2400 Dallas Parkway, Suite 350, Plano, TX 75093. Respondent Rangers Holdings, among other things, is engaged in the provision and sale of outpatient dialysis services as USRC.

5. Respondent Dialysis Parent, LLC (“Dialysis Parent”) is a limited liability company 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 601 Union Street, Suite 3100, Seattle, WA 98101. Dialysis Parent, among other things, is engaged in the provision and sale of outpatient dialysis services as DSI Renal (“DSI”).

6. Respondent Dialysis HoldCo, LLC is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head

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office located at 424 Church Street, Suite 1900, Nashville, TN 37219. Dialysis HoldCo, LLC is a wholly owned subsidiary of Dialysis Parent, LLC.

7. Each 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 company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

8. Pursuant to a Contribution Agreement between Rangers Holdings and Dialysis Parent dated August 21, 2015 (“Agreement”), Rangers Holdings will acquire all of the outstanding membership interests in Dialysis HoldCo, LLC, and, in exchange, Dialysis Parent will receive approximately 44% of the membership interests in Rangers Holdings in a transaction valued at approximately \$640 million (the “Acquisition”).

IV. THE RELEVANT MARKET

9. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the provision of outpatient dialysis services. Most ESRD patients receive dialysis treatments three times per week in sessions lasting between three and five hours while some patients receive treatment at home so they visit the clinic less frequently. ESRD is fatal if not treated with dialysis. The only alternative to outpatient dialysis treatments for patients suffering from ESRD is a kidney transplant. However, the wait time for donor kidneys, during which ESRD patients must receive dialysis treatments, can exceed three years. Additionally, many ESRD patients are not viable transplant candidates. As a result, many ESRD patients have no alternative to dialysis treatments.

10. The relevant geographic market for the provision of dialysis services is defined by the distance ESRD patients are willing and/or able to travel to receive dialysis treatments, and is thus local in nature. Because ESRD patients often suffer from multiple health problems and may require assistance traveling to

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and from the dialysis clinic, these patients are unwilling and/or unable to travel long distances to receive dialysis treatment. As a general rule, ESRD patients do not travel more than thirty miles or thirty minutes to receive dialysis treatment, although travel times and distances vary depending on geographic barriers, travel patterns, and whether an area is urban, suburban, or rural.

11. For the purposes of this Complaint, the geographic market within which to assess the competitive effects of the proposed merger is the area comprised of or within the Laredo, Texas core-based statistical area.

V. THE STRUCTURE OF THE MARKET

12. The market for the provision of outpatient dialysis services is highly concentrated in the local area identified in Paragraph 11. The proposed acquisition would cause the number of providers to be reduced from three to two in the market, leaving only the combined firm and Fresenius Medical Care North America.

13. USRC and DSI are actual and substantial competitors in the relevant market.

VI. ENTRY CONDITIONS

14. The most significant barrier to entry into the relevant market is engaging a nephrologist with an established referral base to serve as the clinic's medical director. By law, each dialysis clinic must have a nephrologist medical director. The medical director is also essential to the competitiveness of the clinic because he or she is the clinic's primary source of referrals. The lack of unaffiliated nephrologists with an established referral stream is a significant barrier to entry into the relevant geographic market identified in Paragraph 11. Additionally, an area must have a low penetration of dialysis clinics and a high ratio of commercial to Medicare patients to attract entry. The absence of these attributes is an additional barrier to entry into the relevant geographic market.

15. The Laredo area does not have available nephrologists or other attributes that would attract entry into the relevant market

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sufficient to deter or counteract the anticompetitive effects described in Paragraph 16.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be substantially to lessen competition in the relevant 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 the following ways, among others:

- a. eliminating actual, direct, and substantial competition between USRC and DSI in the market for the provision of outpatient dialysis services;
- b. increasing the ability of the merged entity unilaterally to raise prices for outpatient dialysis services; and
- c. reducing incentives to improve service or quality in the relevant market.

VIII. VIOLATIONS CHARGED

17. The Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 8, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this seventeenth day of March, 2016, issues its Complaint against said Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Rangers Renal Holdings, LP and US Renal Care, Inc. of Dialysis HoldCo LLC from Dialysis Parent LLC (collectively “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 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 the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, 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, now in further conformity with the procedure described in Commission Rule 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent Rangers Renal Holdings, LP is a Delaware limited partnership, with its office and principal place of business located at 11111 Santa Monica Boulevard, Suite 2000, Los Angeles, CA 90025.
2. Respondent US Renal Care, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office located at 2400 Dallas Parkway, Suite 350, Dallas, TX 75093. US Renal Care, Inc. is a wholly-owned subsidiary of Rangers Renal Holding, LP.
3. Respondent Dialysis Parent, LLC is a limited liability company, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office located at 601 Union Street, Suite 3100, Seattle, WA 98101.
4. Respondent Dialysis HoldCo, LLC is a limited liability company, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office located at 424 Church Street, Suite 1900, Nashville, TN 37219. Dialysis HoldCo, LLC is a wholly-owned subsidiary of Dialysis Parent, LLC.
5. The 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. “US Renal Care” means: (a) Rangers Renal Holdings, LP, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint

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ventures, subsidiaries, divisions, groups, and affiliates controlled by Rangers Renal Holdings, LP, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each, and (b) US Renal Care, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by US Renal Care, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, US Renal Care includes DSI.

- B. “DSI” means (a) Dialysis Parent, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Dialysis Parent, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each, and (b) Dialysis HoldCo, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Dialysis HoldCo, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each .
- C. “Respondents” means US Renal Care and DSI.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer(s) means the following:
 - 1. a Person specified by name in this Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or

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2. a Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Rangers Renal Holding’s acquisition of Respondent Dialysis HoldCo LLC from Respondent Dialysis Parent, LLC.
- G. “Acquisition Date” means the date on which the Acquisition is consummated.
- H. “Clinic” means a facility that provides hemodialysis or peritoneal dialysis services to patients suffering from kidney disease.
- I. “Clinic’s Physician Contracts” means all agreements to provide the services of a Physician to a Clinic, regardless of whether any of the agreements are with a Physician or with a medical group, including, but not limited to, agreements for the services of a medical director for the Clinic and “joinder” agreements with Physicians in the same medical practice as a medical director of the Clinic.
- J. “Confidential Business Information” means competitively sensitive, proprietary, and all other information that is not in the public domain, owned by or pertaining to, a Person or a Person’s business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, patents, technologies, policies and procedures, processes, or other trade secrets.
- K. “Contract Services” means services performed pursuant to any Clinic’s Physician Contract.
- L. “Designated DSI Employee” means each employee of a DSI Laredo Clinic.

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- M. “Divestiture Trustee” means the person appointed to act as Trustee by the Commission pursuant to Paragraph II.A or Paragraph V of this Order.
- N. “DSI Laredo Clinic” or “DSI Laredo Clinics” means any one, or all of following:
1. DSI Laredo Dialysis, located at 5501 Springfield Avenue, Laredo, TX 78041.
 2. DSI South Laredo Dialysis and South Laredo Home, located at 802 Guadalupe Street, Laredo, TX 78040; and
 3. DSI West Laredo Dialysis, located at 4151 Jaime Zapata Memorial Hwy, Ste. 105, Laredo, TX 78046.
- O. “DSI Laredo Clinic Assets” means the following assets relating to the Operation Of A Clinic:
1. all rights under the Clinic’s Physician Contracts;
 2. leases for the Real Property of the DSI Laredo Clinic;
 3. consumable or disposable inventory consistent with the ordinary course of business at the DSI Laredo Clinics including, but not limited to, janitorial, office, medical supplies, dialysis supplies, and pharmaceuticals including, but not limited to, erythropoietin;
 4. all rights, title and interest in any tangible property (except for consumable or disposable inventory) that has been on the premises of the Clinic at any time since June 1, 2015, including, but not limited to, all equipment, furnishings, fixtures, improvements, and appurtenances;

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5. all books, records, files, correspondence, manuals, computer printouts, databases, and other documents relating to the Operation Of A DSI Laredo Clinic, including, but not limited to:
 - a. documents containing information relating to patients (to the extent transferable under applicable law), including, but not limited to, medical records,
 - b. financial records,
 - c. personnel files,
 - d. physician lists and other records of the clinic's dealings with physicians,
 - e. maintenance records,
 - f. documents relating to policies and procedures,
 - g. documents relating to quality control,
 - h. documents relating to payors,
 - i. documents relating to suppliers,
 - j. documents relating to the DSI Laredo Clinics that are also related to the Operation Of Clinics other than the DSI Laredo Clinics, *provided, however,* if such documents are located other than on the premises of the DSI Laredo Clinics, Respondents may divest a copy of the document with the portions not relating to the DSI Laredo Clinics redacted, and
 - k. copies of contracts with Payors and Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of Respondents to make such disclosure.

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6. Respondents' Medicare and Medicaid provider numbers, to the extent transferable;
7. all permits and licenses, to the extent transferable;
8. intangible property relating exclusively to the Operation Of A DSI Laredo Clinic; and a royalty-free perpetual worldwide license for the use, without any limitation, of all other intangible property relating to the Operation Of A DSI Laredo Clinic (including the right to transfer or sublicense such intangible property, exclusively or nonexclusively, to others by any means); and
9. assets that are used in, or necessary for, the Operation Of A DSI Laredo Clinic.

Provided, however, that "assets relating to" does not include Excluded Assets.

- P. "Employee Of A DSI Laredo Clinic" and "Employee Of The DSI Laredo Clinic" mean any individual (including, but not limited to, a clinic director, manager, nurse, technician, clerk, dietician, or social worker) who is employed by Respondents, by an Acquirer, or by another manager or owner of such DSI Laredo Clinic, and who has worked part-time or full-time on the premises of such DSI Laredo Clinic at any time since January 1, 2015, regardless of whether the individual has also worked on the premises of any other Clinic.
- Q. "Excluded Assets" means:
1. all cash, cash equivalents, and short term investments of cash;
 2. accounts receivable;

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3. income tax refunds and tax deposits due to Respondents;
4. unbilled costs and fees, and Medicare bad debt recovery claims, arising before a Clinic is divested to an Acquirer;
5. rights to the names “US Renal Care,” and “DSI,” and any variation of those names (unless otherwise licensed to an Acquirer pursuant to the Order);
6. insurance policies and all claims thereunder;
7. prepaid expenses;
8. minute books (other than governing body minute books of the DSI Laredo Clinic), tax returns, and other corporate books and records;
9. any inter-company balances due to or from Respondents or their affiliates;
10. all benefits plans;
11. all writings and other items that are protected by the attorney-client privilege, the attorney work product doctrine or any other cognizable privilege or protection, except to the extent such information is necessary to the Operation Of A DSI Laredo Clinic;
12. telecommunication systems equipment and applications, and information systems equipment including, but not limited to, computer hardware not physically located at a DSI Laredo Clinic but shared with the DSI Laredo Clinic through local and/or wide area networking systems;
13. computer hardware used in the Operation Of A DSI Laredo Clinic that is (a) not located at the

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Clinic, and (b) not otherwise to be divested pursuant to a Remedial Agreement;

14. all Supplier or provider numbers issued to Respondents by a Supplier or Payor with respect to any DSI Laredo Clinic, except for Respondents' Medicare and Medicaid provider numbers for each DSI Laredo Clinic;
 15. rights under agreements with Payors and Suppliers that are not assignable even if Respondents approve such assignment;
 16. office equipment and furniture that (a) is not, in the ordinary course of business, physically located at the DSI Laredo Clinic, (b) is shared with Clinics other than the DSI Laredo Clinic, and (c) is not necessary to the Operation Of The DSI Laredo Clinic;
 17. Licensed Intangible Property;
 18. Respondents Medical Protocols, subject to the licensing provisions in this Order;
 19. Contracts to which Respondents or their affiliates (other than the DSI Laredo Clinics) are a party and are not otherwise included in the DSI Laredo Clinic Assets; and
 20. strategic planning documents that:
 - a. relate to the Operation Of A Clinic other than a DSI Laredo Clinic, and
 - b. are not located on the premises of a DSI Laredo Clinic.
- R. "Governmental Approvals" means any permissions or sanctions issued by any government or governmental organization, including, but not limited to, licenses,

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permits, accreditations, authorizations, registrations, certifications, certificates of occupancy, and certificates of need.

- S. “Government Approvals For Continued Operation” means any Governmental Approvals, other than Government Approvals For Divestiture, that an Acquirer must have to continue to operate a DSI Laredo Clinic.
- T. “Governmental Approvals For Divestiture” means any Governmental Approvals that an Acquirer must have to own, and to initially operate, a DSI Laredo Clinic, including, but not limited to, state-issued licenses and state-issued certificates of need.
- U. “Intangible Property” means intangible property relating to the Operation Of A DSI Laredo Clinic including, but not limited to, intellectual property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property.
- V. “Laredo, TX Area” means the area in and around Laredo, TX, consisting of the following zip codes: 78040, 78041, 78043, 78044, 78045, 78046, 78067, 78076, 78344, 78360, 78361, and 78369.
- W. “Licensed Intangible Property” means intangible property licensed to Respondents from a third party relating to the Operation Of A DSI Laredo Clinic including, but not limited to, intellectual property, software, computer programs (including, but not limited to, electronic medical record systems), patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the

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modifications or improvements to such intangible property that are licensed to Respondents. (“Licensed Intangible Property” does not mean modifications and improvements to intangible property that are not licensed to Respondents.)

- X. “Medical Protocols” means medical protocols promulgated by Respondents, whether in hard copy or embedded in software, that have been in effect at any time since January 1, 2015, *provided, however*, “Medical Protocols” does not mean medical protocols adopted or promulgated, at any time, by any Physician or by any Acquirer, even if such medical protocols are identical, in whole or in part, to medical protocols promulgated by Respondents.
- Y. “Operation Of A Clinic,” and “Operation Of A DSI Laredo Clinic” mean all activities relating to the business of a Clinic, or a DSI Laredo Clinic, respectively, including, but not limited to:
1. attracting patients to such Clinic for dialysis services, providing dialysis services to patients of such Clinic, and dealing with their Physicians, including, but not limited to, services relating to hemodialysis and peritoneal dialysis;
 2. providing medical products to patients of such Clinic;
 3. maintaining the equipment on the premises of such Clinic, including, but not limited to, the equipment used in providing dialysis services to patients;
 4. purchasing supplies and equipment for such Clinic;
 5. negotiating leases for the premises of such Clinic;
 6. providing counseling and support services to patients receiving products or services from such Clinic;

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7. contracting for the services of medical directors for such Clinic;
 8. dealing with Payors that pay for products or services offered by such Clinic, including but not limited to, negotiating contracts with such Payors and submitting claims to such Payors; and
 9. dealing with Governmental Approvals Relating To such Clinic or that otherwise regulate the Clinic.
- Z. “Ordinary Course Of Business” means actions taken by any Person in the ordinary course of the normal day-to-day Operation Of A Clinic that is consistent with past practices of such Person in the Operation Of A Clinic, including, but not limited to past practice with respect to amount, timing, and frequency.
- AA. “Payor” means any Person that purchases, reimburses for, or otherwise pays for medical goods or services for themselves or for any other person, including, but not limited to: health insurance companies; preferred provider organizations; point of service organizations; prepaid hospital, medical, or other health service plans; health maintenance organizations; government health benefits programs; employers or other persons providing or administering self-insured health benefits programs; and patients who purchase medical goods or services for themselves.
- BB. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- CC. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- DD. “Real Property” means the real property on which, or in which, the DSI Laredo Clinic is located, including

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real property used for parking and for other functions
Relating To the Operation Of A DSI Laredo Clinic.

- EE. “Relating To” means pertaining in any way to, and is not limited to that which pertains exclusively or primarily to.
- FF. “Remedial Agreement” means the following:
1. The Satellite Divestiture Agreement, and
 2. any agreement between a Respondent and an Acquirer, including all amendments, exhibits, attachments, and schedules thereto, related to the DSI Laredo Clinics or DSI Laredo Clinic Assets, that has been approved by the Commission to accomplish the requirements of this Order.
- GG. “Satellite Divestiture Agreement” means the following agreements:
1. the Asset Purchase Agreement dated December 16, 2015, by and among Satellite Healthcare Central States, LLC, Satellite Healthcare, Inc., Dialysis Newco, Inc., and Dialysis Holdco, LLC, and all attachments and exhibits, thereto, and
 2. the Transition Services Agreement, which is an exhibit to the Asset Purchase Agreement, by and between Dialysis Newco, Inc. and Satellite Healthcare Central States, and all attachments and exhibits, thereto.
- The Satellite Divestiture Agreement is attached as Non- Public Appendix A to this Order.
- HH. “Satellite Healthcare” means Satellite Healthcare, Inc., a corporation, organized, existing and doing business under and by virtue of the laws of the State of California with its corporate head office located at 300 Santana Row, Suite 300, San Jose, CA, 95128.

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Satellite Healthcare includes Satellite Healthcare Central States, LLC.

- II. “Software” means executable computer code and the documentation for such computer code, but does not mean data processed by such computer code.
- JJ. “Supplier” means any Person that has sold to Respondents any goods or services, other than Physician services, for use in a DSI Laredo Clinic.
- KK. “Texas Governmental Approvals For Divestiture” means any Governmental Approvals For Divestiture issued by the State of Texas.
- LL. “Time Of Divestiture” means the date upon which the DSI Laredo Clinics and DSI Laredo Clinic Assets are divested to an Acquirer pursuant to this Order.

II.**IT IS FURTHER ORDERED** that:

- A. Respondent US Renal Care shall:
 - 1. Within ten (10) days after the Acquisition Date, divest to Satellite Healthcare, absolutely, and in good faith, pursuant to and in accordance with the Satellite Divestiture Agreements, the DSI Laredo Clinics, and all the DSI Laredo Clinic Assets, as on-going businesses, and grant to the Acquirer a royalty-free, worldwide non-exclusive license for the use, without any limitation, of the Medical Protocols (including the right to transfer or sublicense such protocols, exclusively or nonexclusively, to others by any means). Any failure by Respondents to comply with a Remedial Agreement shall constitute a failure to comply with this Order. The Remedial Agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order. Nothing in this

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Order shall reduce, or be construed to reduce, any rights or benefits of an Acquirer, or any obligations of Respondents, under the Remedial Agreements.

Provided, however, if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Satellite Healthcare, Inc. is not an acceptable Acquirer then, after receipt of such written notification: (1) Respondents shall immediately notify Satellite Healthcare, Inc. of the notice received from the Commission and shall as soon as practicable, but no later than within five (5) business days, effect the rescission of the Satellite Divestiture Agreement; and (2) Respondents shall, within six (6) months of the date Respondents receive notice of such determination from the Commission, divest the DSI Laredo Clinic Assets, as applicable, absolutely and in good faith, at no minimum price, as on-going businesses to an Acquirer or Acquirers that receive the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.

Provided further, however, that if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which any of the divestitures accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture including, but not limited to, entering into additional agreements or arrangements, as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Respondent US Renal Care shall not acquire DSI until it has obtained for all the DSI Laredo Clinics:
1. all approvals for the assignment to the Acquirer of the rights, title, and interest to each lease for Real Property of each DSI Laredo Clinic; and

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2. all approvals for the assignment to the Acquirer of the DSI Laredo Clinic's Physician Contracts;
- C. Respondents shall:
1. place no restrictions on the use by any Acquirer of any of the DSI Laredo Clinic Assets to be divested to such Acquirer, or interfere with or otherwise attempt to interfere with any Acquirer's use of any of the DSI Laredo Clinic Assets to be divested to such Acquirer, including, but not limited to, seeking or requesting the imposition of Governmental Approvals or other governmental restrictions on the Acquirer's business operations relating to the DSI Laredo Clinics.
 2. cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer.
 3. assign to the Acquirer all of the Clinic's Physician Contracts for the DSI Laredo Clinics. *Provided, however,* that (1) if the Acquirer enters into a Clinic Physician Contract for a DSI Laredo Clinic before the DSI Laredo Clinic Assets are divested pursuant to Paragraph II.A. of this Order, and (2) the Acquirer certifies its receipt of such contract and attaches it as part of the Remedial Agreement, then Respondents shall not be required to make the assignment for such DSI Laredo Clinic as required by this Paragraph.
 4. With respect to all contracts other than Clinic's Physician Contracts, at the Acquirer's option and at the Time Of Divestiture of each DSI Laredo Clinic:
 - a. if such contract can be assigned without third party approval, assign Respondents' rights under the contract to the Acquirer; and

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- b. if such contract can be assigned to the Acquirer only with third party approval, assist and cooperate with the Acquirer in obtaining:
 - i. such third party approval and in assigning the contract to the Acquirer, or
 - ii. a new contract.

D. Respondents shall:

1. at the Time Of Divestiture of each DSI Laredo Clinic, provide to the Acquirer of such Clinic contact information about Payors and Suppliers for the Clinic, and
2. not object to the sharing of Payor and Supplier contract terms Relating To the DSI Laredo Clinics: (i) if the Payor or Supplier consents in writing to such disclosure upon a request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with Respondents not to disclose the information to any third party.

E. Respondents shall:

1. if requested by an Acquirer, facilitate interviews between each Designated DSI Employee and the Acquirer, and shall not discourage such employees from participating in such interviews;
2. not interfere in employment negotiations between each Designated DSI Employee and an Acquirer;
3. not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Designated DSI Employee from being employed by an Acquirer, and shall not offer any incentive to the Designated DSI Employee to decline employment with an Acquirer;

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4. cooperate with an Acquirer of a DSI Laredo Clinic in effecting transfer of the Designated DSI Employee to the employ of the Acquirer, if the Designated DSI Employee accepts such offer of employment from an Acquirer;
5. eliminate any contractual provisions or other restrictions that would otherwise prevent the Designated DSI Employee from being employed by an Acquirer;
6. eliminate any confidentiality restrictions that would prevent the Designated DSI Employee who accepts employment with the Acquirer from using or transferring to an Acquirer any information Relating To the Operation Of A DSI Laredo Clinic; and
7. pay, for the benefit of any Designated DSI Employee who accepts employment with an Acquirer, all accrued bonuses, vested pensions and other accrued benefits.

Respondents shall comply with the terms of this Paragraph II.E. from the time Respondents sign the Agreement Containing Consent Order until sixty (60) days after the Time Of Divestiture of each DSI Laredo Clinic for the employees who are Designated DSI Employees .

Provided, however, that if, at any time after the Time of Divestiture, the Acquirer of the DSI Laredo Clinic Assets gives Respondents an unsolicited list of employees to whom the Acquirer does not intend to offer employment, then such employees may be hired by Respondent US Renal Care as full time employees without violating this Paragraph II.E.

Provided, further, however, that no earlier than fifteen (15) days after the Time of Divestiture, Respondents may submit a written request to the Acquirer

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identifying those persons to whom Respondent US Renal Care wishes to offer full time employment; and if the Acquirer within fifteen (15) days of receipt of such request grants, in writing, such request, then Respondent US Renal Care may offer employment to such employees; but if the Acquirer within fifteen (15) days of receipt of such request either: (i) chooses to hire such employees, or (ii) chooses to defer a hiring decision, then Respondents shall continue to comply with the terms of this Paragraph II.E, with regard to such employees.

- F. For a period of two (2) years following the Time Of Divestiture of each DSI Laredo Clinic, Respondent US Renal Care shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any employee who is employed by any Acquirer to terminate his or her employment relationship with such Acquirer, unless that employment relationship has already been terminated by the Acquirer; *provided, however*, Respondent US Renal Care may make general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at any of an Acquirer's employees; *provided, further, however*, Respondent US Renal Care may hire employees who apply for employment with Respondent US Renal Care, as long as such employees were not solicited by Respondent US Renal Care in violation of this Paragraph.
- G. With respect to each Physician who has provided services to a DSI Laredo Clinic pursuant to any of the Clinic's Physician Contracts in effect at any time during the four (4) months preceding the Time Of Divestiture of the Clinic ("Contract Physician"):
1. Respondents shall not offer any incentive to the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group to decline to provide

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services to the DSI Laredo Clinics acquired by the Acquirer, and shall eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the DSI Laredo Clinics any information Relating To the Operation Of A DSI Laredo Clinic; and

2. For a period of three (3) years following the Time Of Divestiture of each DSI Laredo Clinic, Respondent US Renal Care shall not contract for the services of the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group for the provision of Contract Services. *Provided, however,* if the Contract Physician, or the Contract Physician's practice group, or other members of the Contract Physician's practice group were providing services to a Clinic, other than at any of the DSI Laredo Clinics, pursuant to a contract with Respondents in effect as of September 1, 2015, then Respondent US Renal Care may contract with such Contract Physicians, or the Contract Physician's practice group, or other members of the Contract Physician's practice group for services to be provided to that particular Clinic.

H. Respondents shall:

1. not disclose Confidential Business Information relating exclusively to any of the DSI Laredo Clinics to any Person other than the Acquirer of such Clinic; and
2. after the Time Of Divestiture of such Clinic:
 - a. shall not use Confidential Business Information relating exclusively to any of the DSI Laredo Clinics for any purpose other than complying

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with the terms of this Order or with any law;
and

- b. shall destroy all records of Confidential Business Information relating exclusively to any of the DSI Laredo Clinics, except to the extent that: (1) Respondents are required by law to retain such information, and (2) Respondents' inside or outside attorneys may keep one copy solely for archival purposes, but may not disclose such copy to the rest of Respondents.
- I. At the Time Of Divestiture of each DSI Laredo Clinic, Respondents shall provide the Acquirer of the Clinic with manuals, instructions, and specifications sufficient for the Acquirer to access and use any information:
 1. divested to the Acquirer pursuant to this Order, or
 2. in the possession of the Acquirer, and previously used by Respondents in the Operation Of A DSI Laredo Clinic.
 - J. For two (2) years following the Time Of Divestiture of each DSI Laredo Clinic, Respondent US Renal Care shall not solicit the business of any patient who received any goods or services from such Clinic between January 1, 2015, and the date of such divestiture, *Provided, however*, Respondent US Renal Care may (i) make general advertisements for the business of such patients including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at such patients, and (ii) provide advertising and promotions directly to any patient that initiates discussions with, or makes a request to, any Respondent US Renal Care employee.
 - K. Respondents shall convey to the Acquirer of the DSI Laredo Clinics the right to use any Licensed Intangible

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Property (to the extent permitted by the third-party licensor), if such right is needed for the Operation Of A DSI Laredo Clinic by the Acquirer and if the Acquirer is unable, using commercially reasonable efforts, to obtain equivalent rights from other third parties on commercially reasonable terms and conditions.

- L. Respondents shall do nothing to prevent or discourage Suppliers that, prior to the Time Of Divestiture of any DSI Laredo Clinic, supplied goods and services for use in any DSI Laredo Clinic from continuing to supply goods and services for use in such Clinic.
- M. Respondents shall not terminate any transition services agreement that is a part of any Remedial Agreement before the end of the term approved by the Commission without prior approval of the Commission.
- N. The purpose of Paragraph II of this Order is to ensure the continuation of the DSI Laredo Clinics as, or as part of, an ongoing viable enterprises engaged in the same business in which such assets were engaged at the time of the announcement of the Acquisition, to ensure that the DSI Laredo Clinics are operated independently of, and in competition with, Respondents' clinics, and to remedy the lessening of competition alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

- A. For a period of ten (10) years from the date this Order is issued, Respondent US Renal Care shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly:

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1. acquire any assets of or financial interest in any Clinic located in the Laredo, TX Area; or
2. enter into any contract to participate in the management or Operation Of A Clinic located in the Laredo, TX area, except to the extent that the contract relates exclusively to:
 - a. off-site lab services or social worker support materials; or
 - b. billing services, collection services, bookkeeping services, accounting services, supply purchasing and logistics services, or the preparation of financial reports and accounts receivable reports (collectively “Such Services”), where appropriate firewalls and confidentiality agreements are implemented to prevent Confidential Business Information of the Clinic from being disclosed to anyone participating in any way in the operation or management of any Clinic owned by Respondent US Renal Care or any Clinic other than the Clinic to which Such Services are being provided.

Said advance written notification shall contain (i) either a detailed term sheet for the proposed acquisition or the proposed agreement with all attachments, and (ii) documents that would be responsive to Item 4(c) of the Premerger Notification and Report Form under the Hart-Scott-Rodino Premerger Notification Act, Section 7A of the Clayton Act, 15 U.S.C. § 18a, and Rules, 16 C.F.R. § 801-803, Relating To the proposed transaction (hereinafter referred to as “the Notification”). *Provided, however,* (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice, and (iii) the Notification is required from

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Respondent US Renal Care and not from any other party to the transaction. Respondent US Renal Care shall provide the Notification to the Commission at least thirty (30) days prior to consummating the 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), Respondent US Renal Care shall not consummate the transaction until thirty 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.

IV.**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a Monitor to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondent US Renal Care, which consent shall not be unreasonably withheld. If Respondent US Renal Care has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent US Renal Care of the identity of any

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proposed Monitor, Respondent US Renal Care shall be deemed to have consented to the selection of the proposed Monitor.

- C. Not later than ten (10) days after appointment of a Monitor, Respondent US Renal Care shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent US Renal Care's compliance with the terms of this Order, and the Remedial Agreements in a manner consistent with the purposes of this Order.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondents' compliance with the terms of this Order, and the Remedial Agreements, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission, including, but not limited to:
 - a. Assuring that Respondents expeditiously comply with all obligations and perform all responsibilities as required by the this Order, and the Remedial Agreements;
 - b. Monitoring any transition services agreements;
 - c. Assuring that Confidential Business Information is not received or used by Respondents or the Acquirers, except as allowed in this Order.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

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3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of this Order, and the Remedial Agreements.
4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the Ordinary Course Of Business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with their obligations under this Order, and the Remedial Agreements. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order, and the Remedial Agreements.
5. The Monitor shall serve, without bond or other security, at the expense of Respondent US Renal Care on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent US Renal Care, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
6. Respondent US Renal Care shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the

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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 malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.

7. Respondent US Renal Care shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent US Renal Care, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under this Order, and the Remedial Agreements.
 8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under this Order, and the Remedial Agreements.
 9. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants, to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Monitor's duties.

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- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph IV.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order, and the Remedial Agreements.
- H. A Monitor appointed pursuant to this Order may be the same Person appointed as a Trustee pursuant to Paragraph V of this Order.

V.**IT IS FURTHER ORDERED** that:

- A. If Respondent US Renal Care has not divested, absolutely and in good faith and with the Commission's prior approval all of the DSI Laredo Clinic Assets pursuant to Paragraph II of this Order, the Commission may appoint a Divestiture Trustee ("Trustee") to divest any of the DSI Laredo Clinic Assets that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the requirements of Paragraph II of this Order. In the event that the Commission or the 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 US Renal Care shall consent to the appointment of a Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Trustee nor a decision not to appoint a Divestiture 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

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Act, or any other statute enforced by the Commission, for any failure by Respondent US Renal Care to comply with this Order.

- B. The Commission shall select the Trustee, subject to the consent of Respondent US Renal Care, which consent shall not be unreasonably withheld. The Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent US Renal Care has not opposed, in writing, including the reasons for opposing, the selection of any proposed Trustee within ten (10) days after receipt of notice by the staff of the Commission to Respondent US Renal Care of the identity of any proposed Trustee, Respondent US Renal Care shall be deemed to have consented to the selection of the proposed Trustee.
- C. Within ten (10) days after the appointment of a Trustee, Respondent US Renal Care shall execute an agreement that, subject to the prior approval of the Commission, transfers to the Trustee all rights and powers necessary to permit the Trustee to effect the divestitures required by this Order.
- D. If a Trustee is appointed by the Commission or a court pursuant to this Order, Respondent US Renal Care shall consent to the following terms and conditions regarding the Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to divest any of the DSI Laredo Clinic Assets that have not been divested pursuant to Paragraph II of this Order.
 2. The Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the

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end of the twelve (12) month period, the Trustee has submitted a divestiture plan or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Trustee may request. Respondent US Renal Care shall develop such financial or other information as the Trustee may request and shall cooperate with the Trustee. Respondent US Renal Care shall take no action to interfere with or impede the Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent US Renal Care shall extend the time for divestiture under this Paragraph V in an amount equal to the delay, as determined by the Commission or, for a court-appointed Trustee, by the court.
4. The Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent US Renal Care's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner that receives the prior approval of the Commission and to an Acquirer or Acquirers that receive the prior approval of the Commission, as required by this Order; *provided, however*, if the Trustee receives bona fide offers for particular assets from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity for such assets, the

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Trustee shall divest the assets to the acquiring entity selected by Respondent US Renal Care from among those approved by the Commission; *provided, further, however*, that Respondent US Renal Care shall select such entity within five (5) days of receiving notification of the Commission's approval.

5. The Trustee shall serve, without bond or other security, at the cost and expense of Respondent US Renal Care, 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 US Renal Care, 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 the Trustee's services, all remaining monies shall be paid at the direction of Respondent US Renal Care, and the Trustee's power shall be terminated. The compensation of the Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent US Renal Care 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,

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claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Trustee.

7. The Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 8. The Trustee shall report in writing to Respondent US Renal Care and to the Commission every sixty (60) days concerning the Trustee's efforts to accomplish the divestiture.
 9. Respondent US Renal Care may require the Trustee and each of the Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Trustee from providing any information to the Commission.
- E. If the Commission determines that a Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Trustee in the same manner as provided in this Paragraph V.
- F. 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.
- G. The Trustee appointed pursuant to this Paragraph may be the same Person appointed as the Monitor pursuant to the relevant provisions of this Order.

Decision and Order

VI.**IT IS FURTHER ORDERED** that:

- A. From the date Respondents sign the Consent Agreement until the Time of Divestiture, Respondents shall:
1. Maintain each of the DSI Laredo Clinics and all DSI Laredo Clinic Assets in substantially the same condition (except for normal wear and tear) as they existed at the time Respondents sign the Consent Agreement;
 2. Take such actions that are consistent with the past practices of Respondent DSI in connection with each DSI Laredo Clinic and all the DSI Laredo Clinic Assets, and that are taken in the ordinary course of business and in the normal day-to-day operations of the DSI Laredo Clinics;
 3. Keep available the services of the current officers, employees, and agents of Respondent DSI; and maintain the relations and goodwill with suppliers, Payors, physicians, landlords, patients, employees, agents, and others having business relations with the DSI Laredo Clinics and the DSI Laredo Clinic Assets;
 4. Preserve the DSI Laredo Clinics and DSI Laredo Clinic Assets as ongoing businesses and not take any affirmative action, or fail to take any action within Respondents' control, as a result of which the viability, competitiveness, and marketability of the DSI Laredo Clinics and DSI Laredo Clinic Assets would be diminished; and
 5. Not object to sharing with the Acquirer the payor and supplier contract terms relating to the DSI Laredo Clinic Assets: (i) if the payor or supplier consents in writing to such disclosure upon a

Decision and Order

request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with Respondents not to disclose the information to any third party.

- B. The purposes of this Paragraph VI are to: (1) preserve the DSI Laredo Clinics as viable, competitive, and ongoing businesses until the Time of Divestiture, (2) prevent interim harm to competition pending the relevant divestitures and other relief, and (3) help remedy any anticompetitive effects of the Acquisition as alleged in the Commission's Complaint.

VII.**IT IS FURTHER ORDERED** that:

- A. Beginning thirty (30) days after the date this Order is issued, and every sixty (60) days thereafter until Respondent US Renal Care has fully complied with Paragraphs II.A., II.B., II.C., II.D., II.E., II.I., and II.K. of this Order, Respondent US Renal Care shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order, and the Remedial Agreement. Respondent US Renal Care shall submit at the same time a copy of these reports to the Monitor if a Monitor is appointed pursuant to Paragraph IV.
- B. Beginning twelve (12) months after the date this Order is issued, and annually thereafter on the anniversary of the date this Order becomes final, for the next four (9) years, Respondent US Renal Care shall submit to the Commission verified written reports setting forth in detail the manner and form in which it is complying and has complied with this Order, and the Remedial Agreements. Respondent US Renal Care shall submit at the same time a copy of these reports to the Monitor if a monitor is appointed pursuant to Paragraph IV.

Decision and Order

VIII.

IT IS FURTHER ORDERED that Respondent US Renal Care shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent US Renal Care,
- B. Any proposed acquisition, merger or consolidation of Respondent US Renal Care, or
- C. Any other change in Respondent US Renal Care that may affect compliance obligations arising out of this Order, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in Respondent US Renal Care.

IX.

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 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 related to compliance with this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of the Respondents; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

Analysis to Aid Public Comment

X.

IT IS FURTHER ORDERED that this Order shall terminate on March 17, 2026.

By the Commission.

Non-Public Appendix A**Satellite Divestiture Agreement**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Rangers Renal Holdings LP (“Rangers Holdings”), the parent of US Renal Care, Inc. (“USRC”), and Dialysis Holdco, LLC (“Dialysis Holdco”), the parent of Dialysis Newco, Inc. d/b/a DSI Renal (“DSI”). The purpose of the Consent Agreement is to remedy the anticompetitive effects resulting from Rangers Holdings’ purchase of Dialysis Parent, LLC (“Dialysis Parent”). Dialysis Parent is the parent of Dialysis Holdco. Under the terms of the Consent Agreement, USRC is required to divest DSI’s three dialysis clinics in Laredo, Texas.

Analysis to Aid Public Comment

The Consent Agreement has been placed on the public record for 30 days to solicit 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 Consent Agreement and the comments received, and will decide whether it should withdraw from the Consent Agreement, modify it, or make final the Decision and Order (“Order”).

The Transaction

Pursuant to an agreement dated August 21, 2015, Rangers Holdings proposes to acquire all of the outstanding membership interest in Dialysis Holdco from Dialysis Parent in a transaction valued at approximately \$640 million. Dialysis Parent is currently the sole owner of all membership interests in Dialysis Holdco. The Commission’s Complaint alleges that the proposed 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 Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in one market—Laredo, Texas—for the provision of outpatient dialysis services.

The Parties

Privately owned and headquartered in Plano, Texas, USRC is the third-largest provider of outpatient dialysis services in the United States. USRC operates more than 200 outpatient dialysis clinics in 20 states and treats approximately 15,500 patients.

DSI, headquartered in Nashville, Tennessee, is a privately held company and the sixth-largest provider of outpatient dialysis services in the United States. DSI operates 100 dialysis centers, providing dialysis services to approximately 7,500 patients in 22 states.

The Relevant Product and Structure of the Markets

Outpatient dialysis services is the relevant product market in which to assess the effects of the proposed transaction. For patients suffering from End Stage Renal Disease (“ESRD”), dialysis treatments are a life-sustaining therapy that replaces the

Analysis to Aid Public Comment

function of the kidneys by removing toxins and excess fluid from the blood. Most ESRD patients receive dialysis treatment three times per week in sessions lasting between three and five hours. Kidney transplantation is the only alternative to dialysis for ESRD patients. However, the wait-time for donor kidneys – during which ESRD patients must receive dialysis treatments – can exceed five years. Additionally, many ESRD patients are not viable transplant candidates. As a result, ESRD patients have no alternative to dialysis treatments. ESRD patients who are not hospitalized must obtain dialysis treatments from outpatient dialysis clinics.

Dialysis services are provided in local geographic markets limited by the distance ESRD patients are able to travel to receive treatments. ESRD patients are often very ill and suffer from multiple health problems, making travel further than 30 miles or 30 minutes very difficult. As a result, competition among dialysis clinics occurs at a local level, corresponding to metropolitan areas or subsets thereof. The exact contours of each market vary depending on traffic patterns, local geography, and the patient's proximity to the nearest center.

Entry

Entry into the outpatient dialysis services markets identified in the Commission's Complaint is not likely to occur in a timely manner at a level sufficient to deter or counteract the likely anticompetitive effects of the proposed transaction. The primary barrier to entry is the difficulty associated with locating nephrologists with established patient pools to serve as medical directors. By law, each dialysis clinic must have a nephrologist medical director. As a practical matter, medical directors are also essential to the success of a clinic because they are the primary source of referrals. In the relevant geographic market, there are few unencumbered nephrologists and few outside nephrologists willing to move into the area. These obstacles make entry in the affected market more challenging and less likely to avert the anticompetitive effects of the transaction.

Analysis to Aid Public Comment

Effects of Acquisition

The geographic market identified in the Complaint is highly concentrated. The proposed acquisition would cause the number of providers to drop from three to two in this market leaving USRC with a dominant position in Laredo, Texas. The post-acquisition HHI for this market exceeds 4000, and the change in HHI is more than 1200. The evidence shows that health insurance companies and other private payers who pay for dialysis services used by their members benefit from direct competition between USRC and DSI when negotiating rates charged by dialysis providers in this market. The high post-acquisition concentration level, along with the elimination of USRC's and DSI's head-to-head competition suggest the proposed combination likely would result in higher prices for outpatient dialysis services in this geographic market. In addition, the evidence shows that market participants compete for patients on a number of quality measures—including quality of facilities, wait times, operating hours, and location. Given the high post-acquisition concentration level, the proposed combination would likely result in diminished service and quality for patients in Laredo, Texas.

The Consent Agreement

The Consent Agreement remedies the proposed acquisition's anticompetitive effects in the Laredo, Texas market by requiring USRC to divest DSI's three outpatient dialysis clinics to Satellite Healthcare Inc. ("Satellite").

As part of these divestitures, USRC is required to obtain the agreement of the medical director affiliated with the divested clinics to continue providing physician services after the transfer of ownership to the buyer. Similarly, the Consent Agreement requires USRC to obtain the consent of all lessors necessary to assign the leases for the real property associated with the divested clinics to the buyer. These provisions ensure that the buyer will have the assets necessary to operate the divested clinics in a competitive manner.

The Consent Agreement contains several additional provisions designed to ensure that the divestitures are successful. First, the

Analysis to Aid Public Comment

Consent Agreement provides the buyer with the opportunity to interview and hire employees affiliated with the divested clinics and prevents USRC from offering these employees incentives to decline the buyer's offer of employment. This will ensure that the buyer has access to patient care and supervisory staff who are familiar with the clinics' patients and the local physicians. Second, the Consent Agreement prevents USRC from contracting with the medical director affiliated with the divested clinics for three years. This provides the buyer with sufficient time to build goodwill and a working relationship with its medical director before USRC can attempt to capitalize on DSI's prior relationship in soliciting his services. Third, to ensure continuity of patient care and records as the buyer implements its quality care, billing, and supply systems, the Consent Agreement requires USRC to provide transition services for a period up to 12 months. Firewalls and confidentiality agreements have been established to ensure that competitively sensitive information is not exchanged. Fourth, the Consent Agreement requires USRC to provide the buyer with a license to use USRC's policies, procedures, and medical protocols, as well as the option to obtain USRC's medical protocols, which will further enhance the buyer's ability to continue to care for patients in the clinics that will be divested. The Consent Agreement requires USRC to provide notice to the Commission prior to any acquisitions of dialysis clinics in the market addressed by the Consent Agreement in order to ensure that subsequent acquisitions do not adversely impact competition in that market or undermine the remedial goals of the proposed order. Finally, the Consent Agreement allows the Commission to appoint a monitor to oversee USRC's compliance with the Consent Agreement.

The Commission is satisfied that Satellite is a qualified acquirer of the divested assets. Satellite is currently a significant operator of dialysis clinics, operating over 70 outpatient and home dialysis clinics since 1973.

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 proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

Complaint

IN THE MATTER OF

ORACLE CORPORATIONCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4571; File No. 132 3115
Complaint, March 28, 2016 – Decision, March 28, 2016

This consent order addresses Oracle Corporation’s failure to inform consumers that Java SE updates automatically removed only the most recent prior iteration of Java SE installed on the consumer’s computer, even if the consumer had multiple iterations of Java SE installed, and that the update would not remove any iteration released prior to Java SE iteration 6 update 10. The complaint alleges that Oracle violated Section 5(a) of the FTC Act by failing to make such disclosure and left some consumers vulnerable to a serious, well-known, and reasonably foreseeable security risk that attackers would target these computers through exploit kits, resulting in the theft of personal information. The consent order prohibits Oracle from misrepresenting (1) the privacy or security of the covered software on a consumer’s computer, including but not limited to the effect on privacy or security of any installation or update of the covered software; and (2) how to uninstall older iterations of the covered software.

Participants

For the *Commission: Andrea V. Arias and Jacqueline K. Connor.*

For the *Respondent: Jonathan Cedarbaum, D. Reed Freeman, Jr., Jamie Gorelick, Quentin Palfrey, and Benjamin Powell, Wilmer Cutler Pickering Hale and Dorr LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Oracle Corporation 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 Oracle Corporation (“Oracle”) is a Delaware corporation with its principal office or place of business at 500 Oracle Parkway, Redwood City, California 94065.

Complaint

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

ORACLE’S BUSINESS PRACTICES

3. Oracle is a software company that, among other things, develops the Java computing platform (“Java”), which is used to power many types of applications. Some of the more common Java applications allow consumers to play online games, chat with people online, calculate mortgage interest, and view images in 3D. Oracle acquired Java on January 27, 2010, as part of its purchase of Sun Microsystems, Inc.

4. Java comes in multiple editions for both enterprises and consumers. Consumers primarily use the Java Platform, Standard Edition (“Java SE”), which has been installed on more than 850 million personal computers.

5. Java SE includes various components that enable consumers to run Java applications on websites. Many computers today are sold with Java SE pre-installed. Alternatively, a consumer may go to the Java.com website and download Java SE.

JAVA SE SECURITY

6. Since at least 2010, a principal security challenge facing Java SE users was that attackers closely monitored Oracle’s release of updates to its software to identify vulnerabilities in Java SE’s previous iterations. At the same time, attackers often developed malware designed to exploit vulnerabilities in previous iterations of Java SE installed on users’ computers (“exploit kits”).

7. In late 2010, Oracle acknowledged that exploit kits for at least 44 Java SE vulnerabilities were publicly available. For example, attackers have used known exploit kits targeting Java SE vulnerabilities to install key loggers that would capture consumers’ usernames and passwords, which could be used to log into a consumer’s PayPal, bank, and credit card accounts.

Complaint

8. Other Java exploit kits could result in the unauthorized acquisition and transmission of sensitive personal information for the purpose of targeted spear-phishing campaigns.

9. Consumers with insecure iterations of Java SE on their computers were vulnerable to exploit kits targeting Java SE vulnerabilities while browsing infected websites or clicking on nefarious links.

THE JAVA SE UPDATE PROCESS

10. Oracle released Java SE version 6 update 19 in March 2010. Oracle released several subsequent updates for Java SE version 6 through April 16, 2013.

11. When an update was available, consumers would typically receive a prompt to update their Java SE. When the consumer proceeded to install the update, the consumer would encounter a series of installation screens, which stated that “Java provides safe and secure access to the world of amazing Java content,” and that Java SE updates and a consumer’s “system” (*see, e.g.*, Exhibit B) would have “the latest . . . security improvements.” (*See, e.g.*, Exhibits A–B).

12. In its Java SE “update” process, however, Oracle did not inform consumers that Java SE updates automatically removed only the most recent prior iteration of Java SE installed on the consumer’s computer, even if the consumer had multiple iterations of Java SE installed. Updates would also not remove any iteration released prior to Java SE version 6 update 10. Therefore, after the update process, consumers could still have additional older, insecure iterations of Java SE on their computers.

13. Beginning in October 2010, in a separate FAQ page of Oracle’s website, Oracle explained that because, in the past, consumers would install “each Java update . . . in separate directories on [their] system,” consumers “may have installed multiple versions of Java.” (*See, e.g.*, Exhibits C–D). In addition, Oracle explained to consumers that additional “old and unsupported versions of Java on your system present[] a serious

Complaint

security risk” and that “[r]emoving older versions of Java from your system ensures that Java applications will run with the most up-to-date security.” (*See, e.g.*, Exhibits C–D). However, for any consumers sophisticated enough to find this page on their own, it did not inform them that the Java SE update process did not automatically remove all older, insecure iterations of the software. In addition, Oracle failed to disclose this information or link to the relevant FAQ page during the Java SE update process.

14. Oracle was aware, no later than 2011, that its Java SE update process was not sufficient to ensure that consumers could always remove older, insecure iterations of Java SE and, therefore, that Java SE on their systems would have the latest security improvements. In internal documentation, Oracle admitted that “Java malware propagation [was] successful even though [attackers are] exploiting fixed bugs” and that the “Java update mechanism is not aggressive enough or simply not working.” Nevertheless, Oracle did not inform consumers during the update process that updating Java SE did not remove all older iterations of Java SE on their computers, and therefore, that their computers could remain susceptible to exploit kits targeting Java SE vulnerabilities.

15. In July 2011, Oracle released Java SE version 7. Oracle then began to periodically release updates for Java SE version 7. In December 2012, Oracle began to prompt certain users to update from Java SE version 6 to Java SE version 7. These updates continued to remove only the most recent prior iteration of Java SE.

16. In March 2014, Oracle released Java SE version 8. Oracle then began to periodically release updates for Java SE version 8. These updates continued to remove only the most recent prior iteration of Java SE until August 2014.

IMPACT ON CONSUMERS

17. In numerous instances, Java SE’s update and uninstallation issues made it likely that consumers unknowingly would have older, insecure iterations of Java SE installed.

Complaint

18. Attackers used exploit kits to specifically target vulnerabilities in older, insecure iterations of Java SE installed on consumers' computers. As described in Paragraph 7, attackers used these exploit kits to obtain consumers' personal information.

19. By failing to inform consumers that the Java SE update process did not remove all prior iterations of the software, Oracle left some consumers vulnerable to a serious, well-known, and reasonably foreseeable security risk that attackers would target these computers through exploit kits, resulting in the theft of personal information, as described above.

VIOLATION OF THE FTC ACT**Failure to Disclose**

20. As described in Paragraph 11, Oracle represented, directly or indirectly, expressly or by implication, that by updating Java SE, Java users would ensure that Java SE on their computers had the latest security improvements.

21. Oracle failed to disclose, or failed to disclose adequately, that, in numerous instances, updating Java SE would not delete or replace all older iterations of Java SE on a consumer's computer, and as a result, a consumer's computer could still have iterations of Java SE installed that are vulnerable to security risks. This fact would be material to consumers' decision whether to take further action after "updating" Java SE to protect their computers.

22. Oracle's failure to disclose, or disclose adequately, the material information described in Paragraph 21, in light of the representation set forth in Paragraph 20, is a deceptive act or practice.

23. The acts and practices of Oracle 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, 15 U.S.C. § 45(a).

Complaint

THEREFORE, the Federal Trade Commission this twenty-eighth day of March, 2016, has issued this complaint against Oracle.

By the Commission.

Exhibit A



Exhibit A - Windows Java SE version 6 update 20 Update Flow (released by Oracle on April 15, 2010)

Complaint

Exhibit B



1 - Windows Java SE version 7 update 9 Update Flow (released by Oracle on October 16, 2012)

Complaint

Exhibit C

Exhibit C

Why should I remove older versions of Java from my system?, JAVA.COM (Oct. 31, 2010), http://web.archive.org/web/20120626080630/http://www.java.com/en/download/faq/remove_olderversions.xml (accessed by searching for Java.com in the Internet Archive index).

HELP RESOURCES

- [Installing Java](#)
- [Remove Older Versions](#)
- [Using Java](#)
- [FAQ: General Questions](#)
- [FAQ: Mobile Java](#)
- [Support Options](#)

Why should I remove older versions of Java from my system? [Printable Version](#)

This article applies to:

- **Platform(s):** All Platforms
- **Java version(s):** All JRE Versions

The [latest version of Java](#) is always the recommended version as it contains updates and improvements to previous versions. You can confirm that you have the latest version by visiting the [Java Verification](#) page.

Over time, you may have installed multiple versions of Java to run available Java content. In the past, each Java update was installed in separate directories on your system. However, Java updates are now installed in a single directory.

Should I remove older versions of Java?

We highly recommend users to remove all older versions of Java from your system.


Keeping old and unsupported versions of Java on your system presents a serious security risk. Removing older versions of Java from your system ensures that Java applications will run with the most up-to-date security and performance improvements on your system.

How can I remove older versions of Java?

You can safely remove older versions of Java from your system by following the instructions on [Java uninstallation instructions for Windows](#) page.

Do I need older versions of Java?

The latest available version is always compatible with the older versions. However, some Java applications (or applets) can indicate that they are dependent on a particular version, and may not run if you do not have that version installed. If an application or web page you access requires an older version of Java, you should report this to the provider/developer and request that they update the application to be compatible with all Java versions.



Find expert help on Java installation and setup

Get Help Now!

Complaint

Exhibit D

Exhibit D

Why should I remove/uninstall older versions of Java from my system?, JAVA.COM (June 26, 2012), http://web.archive.org/web/20120626080630/http://www.java.com/en/download/faq/remove_olderversions.xml (accessed by searching for Java.com in the Internet Archive index).

HELP RESOURCES

- [Installing Java](#)
- [Remove Older Versions](#)
- [Using Java](#)
- [FAQ: General Questions](#)
- [FAQ: Mobile Java](#)
- [Support Options](#)



Find expert help on Java installation and setup

[Get Help Now!](#)

Why should I uninstall older versions of Java from my system? [Printable Version](#)

The latest version of Java is always the recommended version as it contains feature updates, vulnerability fixes and performance improvements to previous versions. You can confirm that you have the latest version by visiting the [Java Verification](#) page.

Over time, you may have installed multiple versions of Java to run available Java content. In the past, each Java update was installed in a separate directory on your system. However, Java updates are now installed in a single directory.

Should I uninstall older versions of Java?

We highly recommend users uninstall all older versions of Java from your system.

Keeping old and unsupported versions of Java on your system presents a serious security risk.

Uninstalling older versions of Java from your system ensures that Java applications will run with the most up-to-date security and performance improvements on your system.

How can I remove older versions of Java?

You can safely uninstall older versions of Java from your system by following the instructions on [Java uninstallation instructions for Windows](#) page.

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The latest available version is compatible with the older versions. However, some Java applications (or applets) can indicate that they are dependent on a particular version, and may not run if you do not have that version installed. If an application or web page you access requires an older version of Java, you should report this to the provider/developer and request that they update the application to be compatible with all Java versions.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission” or “FTC”), having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and respondent 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 respondent with a violation of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45 *et seq.*;

The respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), which includes: a statement by respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the Consent Agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; 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 violated the FTC 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 for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed by Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following Order:

1. Respondent Oracle Corporation (“Oracle”) is a Delaware corporation with its principal office or place of business at 500 Oracle Parkway, Redwood City, California 94065.

Decision and Order

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:

- A. “Affected Consumers” shall mean persons who, prior to the date of issuance of this order, downloaded, installed, or updated Java SE.
- B. “Clear(ly) and conspicuous(ly)” means that a required disclosure is difficult to miss (*i.e.*, easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication, even if the representation requiring the disclosure is made in only one means.
 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

Decision and Order

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers.
 6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Covered Software” shall mean Oracle’s Java SE, and any other software offered by Oracle directly to consumers to run programs on their computers or applications within a browser. Covered Software does not include software offered exclusively for developers or enterprises.
- E. “Java SE” shall mean Oracle’s Java Platform, Standard Edition software, the Java Runtime Environment (“JRE”), or the Java plug-in offered by Oracle directly to consumers using Windows-based computers. Java SE does not include software offered exclusively for developers or enterprises.
- F. “Iterations” shall mean all releases, other than test releases, that have ever been supported by Oracle.
- G. “Iteration(s) Released Within the Last Quarter” shall mean, at any given point in time, the iteration(s) of Java SE released within the preceding three months.

Decision and Order

- H. Unless otherwise specified, “respondent” shall mean Oracle Corporation, and its successors and assigns.

I.

IT IS ORDERED that respondent and its officers, agents, representatives, and employees, whether acting directly or indirectly, in or affecting commerce, must not misrepresent: (1) the privacy or security of the Covered Software on a consumer’s computer, including but not limited to the effect on privacy or security of any installation or update of the Covered Software; or (2) how to uninstall older Iterations of the Covered Software.

II.

IT IS FURTHER ORDERED that respondent and its officers, agents, representatives, and employees, whether acting directly or indirectly, must ensure that during any installation or update to any Iteration of Java SE released after the date of service of this order, respondent:

- A. Clearly and Conspicuously discloses to the consumer all Iterations of Java SE 1.4.2 or later, other than any Iteration(s) Released Within the Last Quarter, currently installed on the consumer’s computer;
- B. Clearly and Conspicuously explains that there may be risks to the security of the consumer’s computer if the consumer chooses not to remove any Iterations of Java SE older than the Iteration(s) Released Within The Last Quarter currently installed on the consumer’s computer; and
- C. Clearly and Conspicuously discloses which Iterations of Java SE 1.4.2 or later, other than any Iteration(s) Released Within the Last Quarter, that remain installed following installation or update of Java SE, and Clearly and Conspicuously provides instructions describing how consumers can effectively uninstall these Iterations.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent and its officers, agents, representatives, and employees, whether acting directly or indirectly, must notify Affected Consumers, Clearly and Conspicuously that in some instances, they may have older, insecure Iterations of Java SE on their computers. Such notification shall include effective, Clear and Conspicuous instructions on how to remove these older Iterations. Notification shall include, but not be limited to, each of the following means:

- A. Posting of a Clear and Conspicuous hyperlink on the home page of respondent's primary, consumer-facing website for Java SE. Such hyperlink must read "IMPORTANT INFORMATION REGARDING THE SECURITY OF JAVA SE." The hyperlink should connect to a sample of the letter shown in Attachment A. This hyperlink and sample letter must be posted no later than ten (10) days after the date of service of the order and for at least two years following posting;
- B. On or before ten (10) days after the date of service of this order, provide Clear and Conspicuous notice to Affected Consumers regarding the contents of Attachment A. Respondent shall inform Affected Consumers by:
 1. Contacting Avast Software, AVG Technologies, ESET North America, Avira, Inc., McAfee, Inc., Symantec Corporation, Trend Micro, Inc., and Mozilla Corporation to request that these entities publish this notice in their security bulletins;
 2. Sending a Twitter notification via respondent's primary Twitter account for Java SE, the text of which shall read "IMPORTANT INFORMATION REGARDING THE SECURITY OF JAVA SE," and link to a sample of the letter shown in Attachment A; and

Decision and Order

3. Sending a Facebook notification via respondent's primary Facebook account for Java SE, the text of which shall read "IMPORTANT INFORMATION REGARDING THE SECURITY OF JAVA SE," and link to a sample of the letter shown in Attachment A; and
- C. On or before ten (10) days after the date of service of this order and for three (3) years thereafter, providing prompt and free help to Affected Consumers through:
1. An uninstall tool that allows Affected Consumers to uninstall Iterations of Java SE, 1.4.2 or later;
 2. A page on respondent's primary, consumer-facing website for Java SE that Clearly and Conspicuously explains how to uninstall Iterations of Java SE, and provides a link to the uninstall tool referenced in Part III.C.1; and
 3. A Clear and Conspicuous electronic form, specific to update and uninstall issues, available on respondent's primary, consumer-facing website for Java SE. Respondent shall answer within a reasonable time, by email, consumers who fill out such form.

IV.

IT IS FURTHER ORDERED that respondent shall maintain and, upon request, make available to the Federal Trade Commission for inspection and copying, for a period of five (5) years from the date of preparation or dissemination, whichever is later, a print or electronic copy of each document relating to compliance with this order, including but not limited to:

- A. All advertisements, promotional materials, installation and user guides, websites, and installation screens containing any representations covered by this order, as well as all materials used or relied upon in making or disseminating the representation;

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- B. All release notes for all Java SE Iterations, including the Iterations' release dates; and
- C. Any documents, whether prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order.

V.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, must deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, employees, agents, and representatives having managerial or supervisory responsibilities relating to Parts I - III of this order. Respondent must deliver this order to such current subsidiaries and personnel within thirty (30) days after service of this order, and to such future subsidiaries and personnel within thirty (30) days after the person assumes such position or responsibilities. For any business entity resulting from any change in structure set forth in Part VI, delivery must be at least ten (10) days prior to the change in structure. Respondent must secure a signed and dated statement acknowledging receipt of this order, within thirty (30) days of delivery, from all persons receiving a copy of the order pursuant to this section.

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(s) that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor company; 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(s) 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. Unless otherwise directed by a

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representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of Oracle Corporation*, FTC File No. 132 3115. *Provided, however*, that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at Debrief@ftc.gov.

VII.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, within ninety (90) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VIII.

This order will terminate on March 28, 2036, 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 respondent did not violate any provision of the

Decision and Order

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.

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Attachment A**Attachment A**

[To appear with Oracle and Java logos]

SUBJECT: Steps you should take to fix a Java SE security risk on your computer

Dear Java SE customer:

We're sending you this message because you may have downloaded, installed, or updated Java SE software on your computer. The Federal Trade Commission, the nation's consumer protection agency, has sued us for making allegedly deceptive security claims about Java SE. To settle the lawsuit, we agreed to contact you with instructions on how to protect the personal information on your computer by deleting older versions of Java SE from your computer. Please take the suggested steps as soon as possible.

Here's a summary of what the FTC lawsuit is about. The FTC alleged that, in the past, when you installed or updated Java SE, it didn't replace the version already on your computer. Instead, each version installed side-by-side at the same time. Later, after we changed this, installing or updating Java SE removed only the most recent version already on your computer. What's more, in many cases, it didn't remove any version released before October 2008.

Why was that a problem? Earlier versions of Java SE have serious security risks we corrected in later versions. When people downloaded a new version, we said they could keep Java SE on their computer secure by updating to the latest version or by deleting older versions using the Add/Remove Program utility in their Windows system. But according to the FTC, that wasn't sufficient. Updating to the latest version didn't always remove older versions. So many computers had several versions installed.

That creates a serious security vulnerability. Even if you installed the most recent version of Java SE, the personal information on your computer may be at risk because earlier, less secure versions could still be executed.

To fix this problem, visit <http://java.com/uninstall>, where instructions on how to uninstall older versions of Java SE are provided. This webpage also provides a link to the Java SE uninstall tool, which you can use to uninstall older versions of Java SE. You may also go to <http://java.com/uninstallhelp> if you have any additional questions or concerns.

To learn more about this lawsuit, call the FTC at 1-888-922-7836.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order applicable to Oracle Corporation (“Oracle”).

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 and take appropriate action or make final the agreement’s proposed order.

Oracle is a Delaware corporation that, among other things, develops the Java computing platform, which is used to power applications that, for example, allow consumers to play online games, chat with people online, calculate mortgage interest, and view images in 3D. Consumers primarily use the Java Platform, Standard Edition (“Java SE”). When an update to Java SE was available, a consumer would typically receive a prompt to update the software. When the consumer proceeded to install the update, the consumer would encounter a series of installation screens, which stated that “Java provides safe and secure access to the world of amazing Java content,” and that Java SE updates and a consumer’s “system” would have “the latest . . . security improvements.” During the Java SE update process, however, Oracle did not inform consumers that Java SE updates automatically removed only the most recent prior iteration of Java SE installed on the consumer’s computer, even if the consumer had multiple iterations of Java SE installed, and that the update would not remove any iteration released prior to Java SE iteration 6 update 10. As such, after the update process, consumers could still have additional older, insecure iterations of Java SE installed on their computers, which attackers targeted to obtain consumers’ personal information through malware designed to exploit vulnerabilities (“exploit kits”).

The Commission’s complaint alleges that Oracle violated Section 5(a) of the FTC Act by failing to disclose that, in

Analysis to Aid Public Comment

numerous instances, updating Java SE would not delete or replace all older iterations of Java SE on a consumer's computer, and as a result, a consumer's computer could still have iterations of Java SE installed that are vulnerable to security risks. This fact would be material to consumers' decisions whether to take further action after "updating" Java SE to protect their computers, in light of Oracle's representations to consumers that by updating Java SE, users would ensure that Java SE on their computers had the latest security improvements.

The complaint further alleges that, by failing to inform consumers that the Java SE update process did not remove all prior iterations of the software, Oracle left some consumers vulnerable to a serious, well-known, and reasonably foreseeable security risk that attackers would target these computers through exploit kits, resulting in the theft of personal information. Consumers with insecure iterations of Java SE on their computers were vulnerable to exploit kits targeting Java SE vulnerabilities while browsing infected websites or clicking on nefarious links. Attackers used exploit kits targeting Java SE vulnerabilities to install key loggers that captured consumers' usernames and passwords, which could be used to log into a consumer's PayPal, bank, and credit card accounts. Other Java SE exploit kits may have resulted in the unauthorized acquisition and transmission of sensitive personal information for the purpose of targeted spear-phishing campaigns.

The proposed order contains provisions designed to prevent Oracle from engaging in the future in practices similar to those alleged in the complaint.

Part I of the proposed order prohibits Oracle from misrepresenting (1) the privacy or security of the covered software on a consumer's computer, including but not limited to the effect on privacy or security of any installation or update of the covered software; and (2) how to uninstall older iterations of the covered software.

Part II of the proposed order requires Oracle to ensure that during any installation or update of any iteration of Java SE released after the date of service of the order, Oracle:

Analysis to Aid Public Comment

- (1) clearly and conspicuously discloses to the consumer all iterations of Java SE 1.4.2 or later, other than any iteration(s) released within the last quarter, currently installed on the consumer's computer;
- (2) clearly and conspicuously explains that there may be risks to the security of the consumer's computer if the consumer chooses not to remove any iterations of Java SE older than the iteration(s) released within the last quarter currently installed on the consumer's computer; and
- (3) clearly and conspicuously discloses which iterations of Java SE 1.4.2 or later, other than any iteration(s) released within the last quarter, that remain installed following installation or update of Java SE, and clearly and conspicuously provides instructions describing how consumers can effectively uninstall these iterations.

Part III of the proposed order requires Oracle to notify consumers who downloaded, installed, or updated Java SE that, in some instances, they may have older, insecure iterations of Java SE on their computers; and provide instructions to such consumers on how to remove these older iterations. In addition, for three (3) years, Oracle must provide an uninstall tool that allows consumers to uninstall iterations of Java SE 1.4.2 or later; a page on their primary website that explains how to uninstall older, insecure iterations of Java SE; and free support through an electronic form to help consumers with their update and/or uninstall issues.

Parts IV through VIII of the proposed order are standard reporting and compliance provisions. Part IV requires Oracle to retain documents relating to its compliance with the order for a five-year period. Part V requires dissemination of the order now and in the future to all current and future principals, officers, directors, and managers, and to persons with managerial or supervisory responsibilities relating to Parts I – III of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates that Oracle submit a compliance report to the FTC within 90 days, and periodically

Analysis to Aid Public Comment

thereafter as requested. 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 complaint or order or to modify the order’s terms in any way.

Complaint

IN THE MATTER OF

**HIKMA PHARMACEUTICALS PLC,
AND
C.H. BOEHRINGER SOHN AG & CO. KG**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4572; File No. 151 0044
Complaint, March 28, 2016 – Decision, March 28, 2016*

This consent order addresses the \$5 million acquisition by Hikma Pharmaceuticals PLC of certain assets of Ben Venue Laboratories, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening future competition in the markets for acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection in the United States. The consent order requires Hikma to divest the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection to Amphastar Pharmaceuticals, Inc.

Participants

For the *Commission*: Sebastian A. Lorigo.

For the *Respondents*: Jonathan I. Gleklen and Peter J. Levitas, Arnold & Porter LLP; Keira Campbell and David P. Wales, Jones Day.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Hikma Pharmaceuticals PLC (“Hikma”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets of Ben Venue Laboratories Inc., a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG (collectively “Boehringer”) (Hikma and Boehringer hereinafter collectively referred to as

Complaint

“Respondents”), entities subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate 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, 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

1. Respondent Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales, with its corporate office and principal place of business located at 13 Hanover Square, London, W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o: West-Ward Pharmaceuticals, 401 Industrial Way West, Eatontown, NJ 07724.

2. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany with its principal executive offices located at Binger Strasse 173, 55216 Ingelheim, Germany and its United States address for service of process and the Complaint and Decision and Order, as follows: Corporate Secretary, 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. Each Respondent 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 affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Under the terms of a Sale and Purchase Agreement with an effective date of December 4, 2014 (“Agreement”), Hikma proposes to acquire certain assets for approximately \$5 million

Complaint

from Boehringer (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT PRODUCT MARKETS

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic injectable pharmaceutical products:

- a. acyclovir sodium injection;
- b. diltiazem hydrochloride injection;
- c. famotidine injection;
- d. prochlorperazine edisylate injection; and
- e. valproate sodium injection.

IV. THE RELEVANT GEOGRAPHIC MARKET

6. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

7. Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. Three firms, Boehringer, Fresenius Kabi AG (“Fresenius”), and AuroMedics Pharma LLC (“AuroMedics”), currently have Abbreviated New Drug Applications (“ANDAs”) for this drug that have been approved by the U.S. Food and Drug Administration (“FDA”). Only Fresenius and AuroMedics currently supply acyclovir sodium injection to the market. Hikma and one other firm are likely to enter the market in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of acyclovir sodium injection from five to four.

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8. Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. There are four firms that currently have FDA-approved ANDAs for diltiazem hydrochloride injection, Hikma, Boehringer, Hospira, Inc. (“Hospira”), and Akorn, Inc. (“Akorn”), but only Hikma, Hospira, and Akorn currently supply the market. No other firms are likely to enter the market in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.

9. Famotidine injection treats ulcers and gastroesophageal reflux disease. Three firms currently sell the vial presentation of famotidine injection, Hikma, Fresenius, and Mylan N.V. (“Mylan”). Boehringer has an FDA-approved ANDA for famotidine injection vials, but had no sales of the drug in 2014. No other companies have FDA-approved ANDAs for famotidine injection vials. The Acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.

10. Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. Since that time, Heritage Pharmaceuticals Inc. (“Heritage”) has assumed all sales of prochlorperazine edisylate injection. Hikma is the only other company that has an FDA-approved ANDA for prochlorperazine edisylate injection, but it is not currently supplying the market. Another firm has prochlorperazine edisylate injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.

11. Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. There are two firms that currently supply valproate sodium injection in the market, Hikma and Fresenius. Boehringer has an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm has valproate sodium injection in its development pipeline and anticipates achieving

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FDA approval of its ANDA in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

VI. EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or 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, by eliminating future competition between Hikma and the Boehringer assets and reducing the number of generic competitors in the markets for (1) acyclovir sodium injection; (2) diltiazem hydrochloride injection; (3) famotidine injection; (4) prochlorperazine edisylate injection; and (5) valproate sodium injection, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VII. ENTRY CONDITIONS

13. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. Although a limited number of firms other than Respondents plan to begin competing in some relevant markets in the future, such entry would not be sufficient to prevent the competitive harm likely to result from the Acquisition. In addition, no other entry is likely to occur for a substantial amount of time that would eliminate the price increases that will occur after consummation of the Acquisition.

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VIII. VIOLATIONS CHARGED

14. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

15. 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of March, 2016, issues its Complaint against said Respondents.

By the Commission, Commissioner Brill not participating.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Hikma Pharmaceuticals PLC (“Hikma”) of certain assets owned by Ben Venue Laboratories, LLC (as successor to Ben Venue Laboratories, Inc.), a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG (collectively “Boehringer”) (Hikma and Boehringer hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of 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 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

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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 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 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, 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 Decision and Order (“Order”):

1. Respondent Hikma is a corporation organized, existing and doing business under and by virtue of the laws of England and Wales with its principle executive offices located at 13 Hanover Square, London W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o: West-Ward Pharmaceuticals, 401 Industrial Way West, Eatontown, NJ 07724.
2. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany with its principle executive offices located at Binger Strasse 173, 55216 Ingelheim, Germany and its United States address for service of process and the Complaint and Decision and Order, as follows:

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Corporate Secretary, 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. The Commission has jurisdiction over 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 the Order, the following definitions shall apply:

- A. “Hikma” means Hikma Pharmaceuticals, PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Hikma Pharmaceuticals, PLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Hikma shall own the Transferred Assets.
- B. “Boehringer” means C.H. Boehringer Sohn AG & Co. KG its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by C.H. Boehringer Sohn AG & Co. KG (including without limitation, Ben Venue Laboratories, Inc. and Boehringer Ingelheim Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Hikma and Boehringer, individually and collectively.
- D. “Commission” means the Federal Trade Commission.

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- E. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Hikma’s acquisition of certain assets of Respondent Boehringer pursuant to the Acquisition Agreement.
- G. “Acquisition Agreement” means the *Asset Purchase Agreement* dated December 4, 2014, by and among Ben Venue Laboratories, LLC (as successor to Ben Venue Laboratories, Inc.), Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals PLC, to effect the Acquisition among Hikma and Boehringer that was submitted to the Commission.
- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Acyclovir Sodium Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 074596, and any supplements, amendments, or revisions thereto.
- J. “Acyclovir Sodium Injection Product Assets” means all rights, title and interest in and to all assets related to

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the Business of Respondent Boehringer within the Geographic Territory related to each of the Acyclovir Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acyclovir Sodium Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.

- K. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- L. “Amphastar” means Amphastar Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware with its principal executive offices located at 11570 6th Street, Rancho Cucamonga, CA 91730.
- M. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDAs”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to

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21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

- N. “Boehringer Transferred Assets” means the Transferred Assets that are included in the assets to be transferred by Ben Venue Laboratories, LLC to Respondent Hikma pursuant to the Acquisition Agreement.
- O. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.
- P. “Categorized Assets” means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Order in this matter and as are maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;
 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 3. all Product Approvals related to the specified Divestiture Product;
 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

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5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;
8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
 - b. to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive

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notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

- d. to seek cross-referencing from a customer of the Respondents' NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and
 - f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
10. all Product Development Reports related to the specified Divestiture Product;
 11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
 12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the

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specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for each specified Divestiture Product that has been marketed or sold by the Respondents prior to the Closing Date,
 - a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each month for each High Volume Account for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by the Respondent (as that Respondent is identified in the definition of the Divestiture Product) net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and
 - c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average wholesale price; wholesale acquisition cost; and price to Medicare;

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14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
15. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
16. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
17. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
18. all of the Respondents' books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent

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structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- Q. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- R. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

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- S. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- T. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- U. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage

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manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- V. “Diltiazem Hydrochloride Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 074617, and any supplements, amendments, or revisions thereto.
- W. “Diltiazem Hydrochloride Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Diltiazem Hydrochloride Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Diltiazem Hydrochloride Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- X. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

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provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- Y. “Divestiture Agreements” means the following:
1. *Asset Purchase Agreement* by and between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc., dated as of March 4, 2016, and
 2. All amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Divestiture Agreements are the means by which Hikma proposes to divest, transfer, and otherwise convey the Transferred Assets, including the Divestiture Product Assets, to Amphastar, and are contained in Non-Public Appendix I. The Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

- Z. “Divestiture Product(s)” means the following, individually and collectively:
1. Acyclovir Sodium Injection Products;
 2. Diltiazem Hydrochloride Injection Products;
 3. Famotidine Injection Products;
 4. Prochlorperazine Edisylate Injection Products;

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5. Valproate Sodium Injection Products.

AA. “Divestiture Product Assets” means the following, individually and collectively:

1. Acyclovir Sodium Injection Product Assets;
2. Diltiazem Hydrochloride Injection Product Assets;
3. Famotidine Injection Product Assets;
4. Prochlorperazine Edisylate Injection Product Assets;
5. Valproate Sodium Injection Product Assets.

BB. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondents:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
4. to have the specified Divestiture Product(s) made anywhere in the World for distribution or sale

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within, or import into the Geographic Territory;
and

provided however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

- CC. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- DD. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- EE. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- FF. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

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- GG. “Famotidine Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No.’s 075825, 075684, 075622, and 075651, and any supplements, amendments, or revisions thereto.
- HH. “Famotidine Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Famotidine Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Famotidine Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- II. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions.
- JJ. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- KK. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from a Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter

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that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

- LL. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- MM. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- NN. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order.
- OO. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- PP. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- QQ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

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- RR. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- SS. “Prochlorperazine Edisylate Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 040540, and any supplements, amendments, or revisions thereto.
- TT. “Prochlorperazine Edisylate Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Prochlorperazine Edisylate Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Prochlorperazine Edisylate Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- UU. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- VV. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a

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Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

WW. “Product Contracts” means all of the following contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);

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6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of a Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the

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Respondents shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- XX. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that

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Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

YY. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

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17. manufacturing batch records related to the specified Divestiture Product;
 18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- ZZ. “Product Intellectual Property” means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed or controlled by Respondents as of the Closing Date:
1. Patents;
 2. Product Copyrights;
 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
- provided, however,* that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Hikma”, or “Boehringer”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or

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general registered images or symbols by which Hikma, or Boehringer can be identified or defined.

AAA. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed or controlled by Respondents as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
2. in those instances in which Respondents (i) are the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or

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use in any Application related to that Divestiture Product.

BBB. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.

CCC. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*,

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detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

- DDD. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.
- EEE. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- FFF. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- GGG. “Remedial Agreement(s)” means the following:
1. any agreement between a Respondent(s) and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred,

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delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between a Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all

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amendments, exhibits, attachments, agreements, and schedules thereto.

- HHH. “Retained Product” means any Product(s) other than a Divestiture Product.
- III. “Right of Reference or Use” means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.
- JJJ. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,
1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
 2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified

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Divestiture Product that are acceptable to the Acquirer;

3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

KKK. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

LLL. “Third Party(ies)” means any non-governmental Person other than the following: the Respondents; or

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the Acquirer of particular assets or rights pursuant to this Order.

- MMM. “Transferred Assets” means the Transferred Assets as defined in Section 1.02 of the *Asset Purchase Agreement* between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc., March 4, 2016. This *Asset Purchase Agreement* is a Divestiture Agreement and is attached to this Order in Non-Public Appendix I. The Transferred Assets include the Divestiture Product Assets.
- NNN. “Valproate Sodium Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 076295, and any supplements, amendments, or revisions thereto.
- OOO. “Valproate Sodium Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Valproate Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Valproate Sodium Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- PPP. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such

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Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondent Hikma shall divest the Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Amphastar, pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Amphastar, or to reduce any obligations of Respondents, under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Hikma has divested the Divestiture Product Assets to Amphastar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Amphastar is not an acceptable purchaser of the Divestiture Product Assets, then Respondent Hikma shall immediately rescind the transaction with Amphastar, in whole or in part, as directed by the Commission, and shall divest the Divestiture Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

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provided further, however, that if Respondent Hikma has divested the Divestiture Product Assets to Amphastar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Hikma, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets to Amphastar (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date for each respective Divestiture Product, Respondent Hikma shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by the Acquirer for the purposes of the Acquirer determining whether to assume such contracts or agreements.
- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent Hikma to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

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- D. Respondent Hikma shall:
1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
 2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
 4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;

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- b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent who provide assistance to an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.
- E. Upon reasonable written notice and request from the Acquirer, Respondent Hikma shall provide, or cause to be provided to the Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products.

Respondent Hikma shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a

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Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- F. Respondent Hikma shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- G. Not later than thirty (30) days after the Closing Date, Respondent Hikma shall provide written notification of the restrictions on the use and disclosure of the

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Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- H. Respondent Boehringer shall ensure that the Boehringer Transferred Assets are provided to Respondent Hikma without disruption or delay pursuant to the Acquisition Agreement, and, until Respondent Boehringer completely transfers and delivers such Boehringer Transferred Assets to Respondent Hikma, Respondent Boehringer shall:
1. prevent the destruction, removal, wasting, deterioration, or impairment of the Boehringer Transferred Assets;
 2. not sell, transfer, encumber or otherwise impair the Boehringer Transferred Assets (other than as is contemplated by the Acquisition Agreement); and
 3. not take any action that lessens the full economic viability, marketability, or competitiveness of the Boehringer Transferred Assets.

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provided, however, Respondent Boehringer has no obligation hereunder with respect to any Transferred Assets, Divestiture Product Assets, or Categorized Assets other than the Boehringer Transferred Assets.

- I. Until Respondent Hikma divests the Divestiture Product Assets to an Acquirer, Respondent Hikma shall:
 1. prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Product Assets;
 2. not sell, transfer, encumber or otherwise impair the Divestiture Product Assets; and
 3. not take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Product Assets.

- J. Respondent Hikma shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:
 1. any Patent owned by or licensed to Respondent Hikma as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;
 2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to Respondent Hikma at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

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if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. Respondent Hikma shall also covenant to that Acquirer that as a condition of any assignment or license from Respondent Hikma to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from Respondent Hikma that claims inventions conceived by and reduced to practice after the Acquisition Date.

- K. Upon reasonable written notice and request from an Acquirer to Respondent Hikma, Respondent Hikma shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Hikma to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the

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Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

- L. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), that Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent

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that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent's outside counsel related to that Divestiture Product.
- M. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
 2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Agreement Containing Consent Order, and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Hikma, which consent shall

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not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.

- C. Not later than ten (10) days after the appointment of the Monitor, Respondent Hikma shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Monitor is appointed, Respondent Hikma shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
 - 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to

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each Divestiture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Hikma's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Order.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondent Hikma, on such reasonable and customary terms and conditions as the

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Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

- G. Respondent Hikma shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable 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 gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondent Hikma shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

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- I. Respondent Hikma may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, maintain, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, remediate, divest, transfer, deliver or otherwise convey these assets in a

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manner that satisfies the requirements of this Order. In the event that the Commission or the 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, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, remediate, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph,

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Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an

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amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and 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 Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture 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 Divestiture 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 Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of

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Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such

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agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain

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regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent Hikma shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial

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purposes thereof, and provisions to reflect the full scope and breadth of Respondent's obligation to the Acquirer pursuant to this Order.

- D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C., II.D., II.G., II.H., and II.I, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this

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Order to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the Respondents to the relevant Acquirer, and
 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent Hikma shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

VIII.

IT IS FURTHER ORDERED that Respondent Hikma shall notify the Commission at least thirty (30) days prior to:

- C. any proposed dissolution of Respondent;
- D. any proposed acquisition, merger or consolidation of Respondent; or
- E. any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

Decision and Order

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent Hikma made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on March 28, 2026.

By the Commission, Commissioner Brill not participating.

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX I

Asset Purchase Agreement by and between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc. dated March 4, 2016.

[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II

Asset Purchase Agreement among Ben Venue Laboratories, Inc., Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals, dated December 4, 2014.

[Redacted From the Public Record Version, But Incorporated By Reference]

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Hikma Pharmaceuticals PLC (“Hikma”) and C.H. Boehringer Sohn AG & Co. KG (“Boehringer”) that is designed to remedy the anticompetitive effects that otherwise would have resulted from Hikma’s proposed acquisition of forty-nine Abbreviated New Drug Applications (“ANDAs”) from Ben Venue Laboratories,

Analysis to Aid Public Comment

Inc. (“Ben Venue”), a subsidiary of Boehringer, in five generic injectable pharmaceutical markets. Boehringer recently exited the markets related to these ANDAs when it ceased its manufacturing and other operations through Ben Venue. Under the terms of the proposed Consent Agreement, Hikma is required to divest to Amphastar Pharmaceuticals, Inc. (“Amphastar”) the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, or make final the Decision and Order (“Order”).

Pursuant to a Sale and Purchase Agreement dated December 4, 2014 (“Proposed Acquisition”), Hikma proposes to acquire forty-nine ANDAs from Boehringer for approximately \$5 million. The Commission alleges in its Complaint that the Proposed 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 Commission Act, as amended, 15 U.S.C. § 45, by lessening future competition in the markets for acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection in the United States. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

I. The Relevant Products and Structure of the Markets

The relevant products are all generic versions of injectable pharmaceutical products. Generic versions of these products are usually launched after a branded product’s patents expire, or a

Analysis to Aid Public Comment

generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. Sometimes, however, a branded injectable drug manufacturer may choose to lower its price and compete against generic versions of the drug, in which case it would be a participant in the generic drug market.

The relevant products at issue and the structure of each of the relevant markets is as follows:

- Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. Three firms, Boehringer, Fresenius Kabi AG (“Fresenius”), and AuroMedics Pharma LLC (“AuroMedics”), currently have ANDAs for this drug that have been approved by the U.S. Food and Drug Administration (“FDA”). Only Fresenius and AuroMedics currently supply acyclovir sodium injection to the market. Hikma and one other firm are likely to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of acyclovir sodium injection from five to four.
- Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. There are four firms that currently have FDA-approved ANDAs for diltiazem hydrochloride injection, Hikma, Boehringer, Hospira, Inc. (“Hospira”), and Akorn, Inc. (“Akorn”), but only Hikma, Hospira, and Akorn currently supply the market. No other firms are likely to enter the market in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.

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- Famotidine injection treats ulcers and gastroesophageal reflux disease. Three firms currently sell the vial presentation of famotidine injection, Hikma, Fresenius, and Mylan N.V. Boehringer has an FDA-approved ANDA for famotidine injection vials, but had no sales of the drug in 2014. No other companies appear to be poised to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.
- Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. Since that time, Heritage Pharmaceuticals Inc. has assumed all sales of prochlorperazine edisylate injection. Hikma is the only other company that has an FDA-approved ANDA for prochlorperazine edisylate injection, but it is not currently supplying the market. Another firm has prochlorperazine edisylate injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.
- Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. There are two firms that currently supply valproate sodium injection in the market, Hikma and Fresenius. Boehringer has an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm has valproate sodium injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

Analysis to Aid Public Comment

II. Competitive Effects

The transaction will reduce competition by decreasing the number of future suppliers in each of these markets; in generic pharmaceutical products, prices generally decrease as the number of competing generic suppliers increases. In addition, the injectable pharmaceutical industry generally, and the generic products at issue in this investigation in particular, are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities of, and contributed to price increases of, several of the generic injectable products impacted by this transaction. By reducing the number of likely future competitors in these markets, the Proposed Acquisition will likely create a direct and substantial anticompetitive effect on prices for each of the relevant products, absent the remedies required by the proposed Consent Agreement.

In each of the relevant markets, either Hikma or Boehringer, or both, currently do not supply an existing generic product. For markets in which Hikma is not a current competitor, it is likely to become one in the near future. Boehringer has recently exited each of these markets, but, absent the Proposed Acquisition, it would have had the incentive to sell these ANDAs to a third-party supplier who would likely bring these products to market. Hikma, which already has an approved ANDA or is likely to soon achieve FDA approval for an ANDA in each of the five relevant markets at issue, lacks that incentive, and thus, customers would be deprived of the price decreases that likely would have accompanied third-party entry into each of these concentrated markets.

III. Entry

Entry into each of these generic injectable product markets will not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years.

Analysis to Aid Public Comment

IV. The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Hikma is required to divest the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection to Amphastar. Hikma must accomplish these divestitures and relinquish its rights no later than ten days after the acquisition.

Amphastar is a global pharmaceutical company based in Rancho Cucamonga, California and has over 1,200 employees worldwide. The company owns five pharmaceutical manufacturing facilities and produces a variety of branded and generic pharmaceutical products. Amphastar manufactures and sells sixteen injectable drug products in the United States, as well as a broad range of other pharmaceutical dosage formulations, including emulsions, suspensions, jellies, and lyophilized products. The company sells most of its products through long-standing relationships with major group purchasing organizations, drug wholesalers, and retailers in the United States. With its experience in generic markets, and in injectable products in particular, Amphastar is expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Amphastar is not an acceptable acquirer, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Amphastar and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The

Analysis to Aid Public Comment

Order requires Boehringer to maintain the economic viability, marketability, and competitiveness of the assets to be divested until they are transferred to Hikma, and requires Hikma to do the same until such time as they are transferred to a Commission-approved acquirer. The Order also requires that the parties transfer all confidential business information, regulatory, formulation, and manufacturing reports, as well as provide access to employees who possess or are able to identify such information. Because the products related to the Boehringer (Ben Venue) ANDA assets have already exited the market, the Order does not require a transitional supply agreement.

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

Complaint

IN THE MATTER OF

**GENERAL WORKINGS INC. D/B/A VULCUN,
ALI MOIZ
AND
MURTAZA HUSSAIN**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4573; File No. 152 3159
Complaint, April 18, 2016 – Decision, April 18, 2016*

This consent order addresses General Workings Inc.'s replacement of a popular browser-based game called *Running Fred* with their own software program, called *Weekly Android Apps*, on users' desktops, which contained code that would install, without adequate disclosure to users, apps on user's mobile devices, without informing consumers. The complaint alleges that Respondents installed software, including Chrome browser extensions and mobile apps, onto users' desktops and mobile devices without adequately disclosing to users that the software would be installed. The consent order requires Respondents to clearly and conspicuously disclose the types of information their products and services will access, how that information will be used, and the nature of any changes to Respondents' products and services. The order also requires Respondents to display built-in permission notices or approvals, and to obtain consumer's express affirmative consent prior to installation or material changes of any product or service.

Participants

For the *Commission*: Alexander E. Reicher and Jacob Snow.

For the *Respondents*: Nate Garhart, Cobalt LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that General Workings Inc., a corporation, and Ali Moiz and Murtaza Hussain, individually and as officers of the corporation (collectively "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:

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1. Respondent General Workings Inc., also doing business as Vulcun (“Vulcun”), is a Delaware corporation with its principal office or place of business at 424 Clay Street, San Francisco, California 94111.

2. Respondent Ali Moiz is a founder and officer of Vulcun. Individually or in concert with others, he controlled or had the authority to control, or participated in, the acts and practices of Vulcun, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Vulcun.

3. Respondent Murtaza Hussain is a founder and officer of Vulcun. Individually or in concert with others, he controlled or had the authority to control, or participated in, the acts and practices of the Vulcun, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Vulcun.

4. As described below, Respondents installed software, including Chrome browser extensions and mobile apps, onto users’ desktops and mobile devices without adequately disclosing to users that the software would be installed. Respondents’ conduct had two parts. First, Respondents acquired a popular browser-based game called *Running Fred* and replaced it entirely with their own software program, called *Weekly Android Apps*, on users’ desktops. Users of *Running Fred* were not informed that the game had been replaced. Second, *Weekly Android Apps* contained code that would install, again without adequate disclosure to users, apps on user’s mobile devices.

5. 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.

Desktop Computer Browser Extensions

6. Google, Inc. (“Google”) offers a web browser, Chrome, as a free download for desktop computer and mobile operating systems. The desktop-computer version of Chrome allows users to install “extensions,” which are software programs that can

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modify and extend Chrome's functionality. Extensions are created using web technologies like HTML, JavaScript, and Cascading Style Sheets. Extensions can perform minimal functions in the browser, like displaying the number of unread emails in a user's account. But they also can operate as complete, independent programs. Among the available Chrome browser extensions are games, news readers, video-streaming clients, project-management applications, and many others. Chrome browser extensions currently run only in the desktop-computer version of Chrome; the version of Chrome for mobile operating systems does not allow the use of extensions.

7. The Chrome Web Store is Google's portal for consumers to find and install extensions in their Chrome web browser. Similar to a mobile-app store like the Google Play Store, the Chrome Web Store allows users to view information about extensions that are offered by developers and also to install those extensions. The Chrome Web Store displays, for example, user reviews and ratings of available Chrome browser extensions. The Chrome Web Store also displays the number of users who have installed each extension. When users comment or review an extension, it is possible for the developer of the extension to write a response to the review. These reviews, and any responses, are then visible to consumers browsing the Chrome Web Store.

Installation of Mobile Apps

8. The Google Play Store is Google's portal for consumers to find and install apps on devices running the Android mobile operating system. The Google Play Store is accessible through a website on a desktop-computer browser and through a standalone Android app.

9. Some users can only install mobile apps from their mobile devices. Other users have configured their accounts to allow their desktop computers, through the Google Play Store, to install Android apps on their mobile devices.

10. When users install a mobile app (whether they do so from a desktop computer or mobile device), the user is presented with a window describing what information, including sensitive

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information (e.g., location information) or sensitive device functionality (e.g., the ability to take photos with the device's camera), an app may access. The installation process allows users to decline to install an app if they do not wish to grant the app's requested permissions.

The Takeover of *Running Fred*

11. Chrome browser extensions are associated in the Chrome Web Store with particular developers or other entities. Dedalord, LLC, a game developer, offered a browser extension, *Running Fred*, in the Chrome Web Store. *Running Fred* became a popular Chrome-extension game with a large number of users. *Running Fred* had more than 200,000 users and an average star rating of 4.5 stars (out of 5 possible stars) with approximately 2,300 reviews.

12. On or around September 9, 2014, Respondents acquired control of *Running Fred*. Shortly thereafter, Respondents replaced *Running Fred* on these users' browsers with another Chrome browser extension called *Weekly Android Apps*. The users of *Running Fred* were not notified that *Running Fred* had been replaced.

Respondents' Advertising of *Weekly Android Apps*

13. After replacing *Running Fred* with *Weekly Android Apps*, Respondents continued to advertise and distribute Chrome Extensions called *Weekly Android Apps* and *Apps by Cindy* to consumers via the Chrome Web Store. In the Chrome Web Store, Respondents stated that *Weekly Android Apps* offered consumers "the hottest mobile apps." Moreover, Respondents claimed the apps selected would be "hand picked" and not influenced by payments from developers. Exhibit A (screen shot from Chrome Web Store). In fact, Respondents did accept payments from at least one developer of an apps that was included in *Weekly Android Apps*. Respondents also claimed—inaccurately—that their extensions, which includes *Weekly Android Apps*, had been featured on prominent tech sites, such as MacRumors, Engadget, and Lifehacker. Further, Respondents claimed—again

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inaccurately—that *Apps by Cindy* had been selected as “one of the best mobile blogs of 2013” by RunMobile.

14. Consumers often install extensions based on the popularity and star rating of Chrome browser extensions in the Chrome Web Store. After the takeover of *Running Fred*, the information page for *Weekly Android Apps* on the Chrome Web Store stated that it had more than 200,000 users, 2,300 reviews, and an average 4.5-star-rating. Exhibit B (screen shot from Chrome Web Store). This user count and star rating, however, primarily reflected the user count and star rating associated with *Running Fred*. Few, if any of, these users had ever rated or used *Weekly Android Apps*.

**Disruption of Users’ Experience on Mobile Devices and
Desktop Computers**

15. Once installed on users’ desktop computers, *Weekly Android Apps* force-installed apps onto those users’ mobile devices. *Weekly Android Apps* accomplished this by preventing users from reviewing the Android permissions associated with the apps that it installed onto users’ mobile devices. These permissions would have shown the user what information or device functionality the apps could access. Code in *Weekly Android Apps* hid these permissions and automatically approved the default Android permissions request associated with the apps without the user’s knowledge. *Weekly Android Apps*, after taking over *Running Fred*, installed numerous apps using this code, including one solitaire game and a second app called *myphoneemails*.

16. *Weekly Android Apps* significantly disrupted users’ operation of their desktop computers. *Weekly Android Apps* opened additional windows and also reset the users’ home page for their browsers. Desktop-computer users saw new tabs or windows open repeatedly. When users closed the new windows, others would pop up. One user complained that “[t]his was installed automatically somehow, it has something to do with a . . . bug that has infected my chromebook[.] [O]n [C]hrome I have tabs opening by themselves advertising this poker and other [P]lay [S]tore items saying ‘click here to install on your phone[.]’ I have never authorized this tab[.] Please stop these people!!!!”

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Another user stated that “I didn’t ask for this extension to be installed, and there was no notification that it was being installed, yet it just showed up in my browser! I only found out about it because Chrome informed me that it was taking over my home page! How did this happen?”

17. *Weekly Android Apps* also significantly disrupted users’ operation of their mobile devices without appropriate consent. Once *Weekly Android Apps* was installed on user’s desktop browsers, it would redirect the users’ browsers to the Google Play Store. Once at the Google Play Store, *Weekly Android Apps* would detect and click the “Buy” buttons associated with certain mobile apps without notifying the user. *Weekly Android Apps* would also accept the Android permission notification without notifying the user. As a result, mobile-device users found unexpected and unfamiliar apps on their devices, and, when users sought to delete those apps, new ones reappeared, without any action from the users. One user complained that the mobile app “keeps reinstalling itself. . . . It’s happening to my wife’s phone too. Help!” Another user complained that “[i]t continuously installs itself to my system without my consent no matter how many times I try to uninstall it. Others are also experiencing this. This ‘application’ might be a virus.”

18. Because the *Weekly Android Apps* hid and accepted the default Android permissions request, these mobile apps could have gained immediate access to the user’s address book, photos, location, and persistent device identifiers. In addition, once installed, the apps could have gained access to other information, including financial and health information, by executing additional malicious code on the consumer’s mobile device.

COUNT I
Unfair Practice

19. As described in paragraphs 11 through 18, Respondents installed *Weekly Android Apps* on more than 200,000 users’ browsers without adequate notice to the users or consent for the installation. Users whose desktop and mobile devices were compromised had their experience of using their devices seriously disrupted. Moreover, *Weekly Android Apps* allowed Respondents

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to force-install apps onto users' mobile devices. The force-installed apps on users' mobile devices also repeatedly reappeared after users attempted to remove them. These actions seriously interfered with the consumers' use of their desktop computers and mobile devices. In addition, any apps force-installed on users' mobile devices could have provided Respondents and the app developer with access to private, sensitive information stored on the users' mobile devices, including user's address book, photos, location, persistent device identifiers, and medical and financial information. Respondents' conduct has caused or is likely to cause substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers themselves. Respondents' conduct is an unfair act or practice.

COUNT II
False Claims

20. In connection with the advertising, promotion, or distribution of *Weekly Android Apps*, Respondents have represented, directly or indirectly, expressly or by implication, that:

- a. *Weekly Android Apps* provides impartial, independent selections of apps.
- b. *Weekly Android Apps* has been featured on prominent tech sites, such as MacRumors, Engadget and Lifehacker.
- c. *Apps by Cindy* has been selected as one of the best mobile blogs of 2013 by RunMobile.
- d. *Weekly Android Apps* has been installed by more than 200,000 users.
- e. *Weekly Android Apps* had more than 2,300 reviews and an average rating of 4.5 out of 5 stars.

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21. In truth and in fact:

- a. *Weekly Android Apps* did not provide impartial, independent selections of apps. Respondents received some financial compensation in return for installing the developers' apps on consumers' mobile devices.
- b. *Weekly Android Apps* had not been featured on prominent tech sites such as MacRumors, Engadget, and Lifehacker.
- c. *Apps by Cindy* has not been selected as one of the best mobile blogs of 2013 by RunMobile.
- d. *Weekly Android Apps* had not been installed by more than 200,000 users. Rather, the vast majority of these users had installed *Running Fred*, not *Weekly Android Apps*.
- e. *Weekly Android Apps* did not have more than 2,300 reviews and an average rating of 4.5 out of 5 stars. The vast majority of these ratings were from *Running Fred* users, not *Weekly Android Apps* users.

22. Therefore, the representations set forth in Paragraph 20 were, and are, false and misleading.

Violations of Section 5

23. 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 eighteenth day of April, 2016, has issued this complaint against Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“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 a complaint which the Western Region–San Francisco proposed to present to the Commission for its consideration and which, if issued, would charge the Respondents with violations of the Federal Trade Commission Act; and

The Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“consent agreement”), which includes: a statement by Respondents that they neither admit nor deny any of the allegations in the draft complaint except as specifically stated in the consent agreement, and, only for purposes of this action, admit the facts necessary to establish jurisdiction; 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 Federal Trade Commission 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 for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent General Workings Inc., also doing business as Vulcun, is a Delaware corporation with its principal office or place of business at 930 Montgomery Street, Suite 301, San Francisco, California 94111.

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2. Respondent Ali Moiz is a founder and officer of General Workings. His principal office or place of business is the same as that of General Workings.
3. Respondent Murtaza Hussain is a founder and officer of General Workings. His principal office or place of business is the same as that of General Workings.
4. 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:

- A. Unless otherwise specified, “Respondents” shall mean General Workings Inc., a corporation, also doing business as General Workings, its successors and assigns; and Ali Moiz and Murtaza Hussain, individually and as officers of the corporation.
- B. “Affected Consumers” shall mean all persons who, prior to December 1, 2014, had *Running Fred, Weekly Android Apps*, or other related applications present on their web browser; or (b) had applications installed on any mobile device or computer through *Weekly Android Apps* or another related application.
- C. “Clearly and conspicuously” means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the

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communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication, even if the representation requiring the disclosure is made in only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

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- D. “Covered Information” shall mean 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; (d) a telephone number; (e) a Social Security number; (f) a driver’s license or other state-issued identification number; (g) a financial institution account number; (h) credit or debit card information; (i) a persistent identifier, such as a customer number held in a “cookie,” a static Internet Protocol (“IP”) address, a mobile device ID, or processor serial number; (j) precise geolocation data of an individual or mobile device, including but not limited to GPS-based, WiFi-based, or cell-based location information (“geolocation information”); (k) an authentication credential, such as a username and password; or (l) any other communications or content stored on a consumer’s mobile device.
- E. “Covered Products or Services” shall mean any product or service offered or operated by any Respondent, including, but not limited, to any (a) browser extension, (b) website or web service, or (c) mobile app.
- F. “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 and their officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any Covered Products or Services, in or affecting commerce, shall not misrepresent in any manner, expressly or by implication:

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- A. The existence of any connection between an endorser and a provider of such Covered Products or Services that might materially affect the weight or credibility of the endorsement;
- B. The nature of such Covered Products or Services installed, downloaded, reviewed, or endorsed by consumers;
- C. The number of consumers that have installed, downloaded, used, reviewed, or endorsed such Covered Products or Services;
- D. The nature of press coverage received by such Covered Products or Services;
- E. The extent to which Covered Information is collected, used, disclosed, or shared;
- F. The extent to which users may exercise control over the collection, use, disclosure, or sharing of Covered Information;
- G. The purpose(s) for which any Covered Information will be collected, used, disclosed, or shared; or
- H. The extent to which any Respondent uses, maintains, and protects the privacy, confidentiality, security, or integrity of covered information collected from or about consumers.

II.

IT IS FURTHER ORDERED that Respondents and their officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, shall not offer a product or service or materially change a Covered Product or Service unless prior to the consumer downloading or installing it, Respondents:

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- A. Disclose, clearly and conspicuously, the following:
1. The types of information the Covered Product or Service will access and how that information will be used to perform any services related to the Covered Product or Service; and
 2. The nature of any material change to a Covered Product or Service;
- B. Display any built-in permissions notice or approval request associated with the installation of any product or service; and
- C. Obtain the consumer's express affirmative consent prior to the installation of the product or service and prior to any subsequent installation of any other product or service or any material change to a Covered Product or Service.

III.

IT IS FURTHER ORDERED that Respondents, within ten (10) days from the date of entry of this Order, shall delete all Covered Information relating to Affected Consumers that is within their possession, custody, or control and was collected at any time prior to the date of entry of this Order. Covered Information need not be disposed of, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

Provided, however, that any Covered Information that Respondents currently possess that must be maintained under Part IV of this Order shall not be deleted.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years from the entry of this order or after the last date of dissemination of any representation covered by this order,

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whichever is later, 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 but not limited to Respondents' terms of use, end-user license agreements, frequently asked questions, privacy policies, and other documents publicly disseminated relating to: (a) the collection of data; (b) the use, disclosure or sharing of such data; and (c) opt-out practices and other mechanisms to limit or prevent such collection of data or the use, disclosure, or sharing of data;
- B. All materials that were relied upon in disseminating the representation;
- C. Complaints or inquiries relating to any Covered Product or Service, and any responses to those complaints or inquiries; and
- D. Documents that are sufficient to demonstrate compliance with each provision 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, for the next five (5) years, 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

VI.

IT IS FURTHER ORDERED that Respondent General Workings Inc, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) 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. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *In the Matter of General Workings Inc.*, File No. 152-3159.VII.

VII.

IT IS FURTHER ORDERED that Respondents Ali Moiz and Murtaza Hussain, for a period of five (5) years after the date of issuance of this order, shall 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 each Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject

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line must begin: *In the Matter of General Workings Inc.*, File No. 152-3159.

VIII.

IT IS FURTHER ORDERED that Respondents, within sixty (60) days after the date of service of this order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *In the Matter of General Workings Inc.*, 152-3159.

IX.

This order will terminate on April 18, 2036, 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

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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 OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing consent order from General Workings Inc., Ali Moiz, and Murtaza Hussain (collectively “Respondents”).

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 and take appropriate action or make final the agreement’s proposed order.

Respondent General Workings Inc., also doing business as Vulcun, is a Delaware corporation with its principal office or place of business in San Francisco, California. Respondents Ali Moiz and Murtaza Hussain are founders and officers of Vulcun. The Commission’s complaint alleges that Respondents installed software, including Chrome browser extensions and mobile apps, onto users’ desktops and mobile devices without adequately disclosing to users that the software would be installed. Google offers a web browser, Chrome, as a free download for desktop computer and mobile operating systems. The desktop-computer version of Chrome allows users to install “browser extensions,” which are software programs that can modify and extend

Analysis to Aid Public Comment

Chrome's functionality. Respondents' conduct had two parts. First, Respondents acquired a popular browser-based game called *Running Fred* and replaced it entirely with their own software program, called *Weekly Android Apps*, on users' desktops. Users of *Running Fred* were not informed that the game had been replaced. Second, *Weekly Android Apps* contained code that would install, again without adequate disclosure to users, apps on user's mobile devices.

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

Part I of the proposed order prohibits Respondents from misrepresenting certain aspects of any browser extension, website, web service, mobile app, or any other product or service they offer or operate. Specifically, Respondents are prohibited from misrepresenting: the existence of certain endorsements; the nature of their products and services; the installation, download, usage, review, or endorsement statistics associated with their products and services; the press coverage of their products and services; their information collection, usage, disclosure, and sharing practices; the extent of user control over information about individual consumers; the purpose of collecting, using, disclosing, or sharing information about individual consumers; and the extent to which Respondents protect the privacy, confidentiality, security, and integrity of information collected from or about consumers.

Part II of the proposed order requires Respondents to clearly and conspicuously disclose the types of information their products and services will access, how that information will be used, and the nature of any changes to Respondents' products and services. The order also requires Respondents to display built-in permission notices or approvals, and to obtain consumer's express affirmative consent prior to installation or material changes of any product or service.

Part III of the proposed order requires Respondents to delete certain information collected about individual consumers within ten days of entry of the order.

Analysis to Aid Public Comment

Part IV of the proposed order contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Parts V, VI, VII, and VIII of the proposed order require Respondents to: deliver a copy of the order to certain personnel who have responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; notify the Commission of changes in the employment of Respondents Moiz and Hussain; and file compliance reports with the Commission.

Part IX of the proposed order provides that the order will terminate after twenty (20) years, with certain exceptions.

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 complaint or proposed order, or to modify the proposed order's terms in any way.

Complaint

IN THE MATTER OF

**LUPIN LTD,
GAVIS PHARMACEUTICALS LLC,
AND
NOVEL LABORATORIES, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4566; File No. 151 0202
Complaint, February 18, 2016 – Decision, April 20, 2016*

This consent order addresses the \$850 million acquisition by Lupin Ltd. of certain assets of Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. The complaint alleges that the acquisitions, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the market for generic doxycycline monohydrate capsules and future competition in the market for generic mesalamine ER capsules in the United States. The consent order requires the parties to divest all of Gavis's rights and assets related to generic doxycycline monohydrate capsules and generic mesalamine extended release capsules to G&W Laboratories.

Participants

For the *Commission*: Jennifer Lee and Kari A. Wallace.

For the *Respondents*: Hill B. Wellford III, Morgan Lewis & Bockius LLP; Amanda P. Reeves, Latham & Watkins LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Lupin Ltd. ("Lupin"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondents Gavis Pharmaceuticals Inc. ("Gavis") and Novel Laboratories, Inc. ("Novel"), corporations subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisitions, if

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consummated, would violate 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, 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

1. Respondent Lupin is a corporation organized, existing and doing business under and by virtue of the laws of India with its principal executive offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 200 051, India, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, MD 21202.

2. Respondent Gavis is a limited liability corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

3. Respondent Novel is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

4. Each Respondent 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 company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITIONS

5. Pursuant to Purchase and Sale Agreements dated July 23, 2015, Lupin plans to acquire (1) all of the outstanding interests of Gavis for approximately \$765.6 million; and (2) all of the voting securities of Novel for approximately \$83.6 million (the

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“Acquisitions”). Gavis and Novel are related companies: Novel specializes in the development and manufacture of generic products while Gavis markets and sells the products developed by Novel. The Acquisitions are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisitions are the development, license, manufacture, marketing, distribution, and sale of the following pharmaceutical products:

- a. generic doxycycline monohydrate capsules; and
- b. generic mesalamine extended release (“ER”) capsules.

7. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisitions in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

8. Generic doxycycline monohydrate capsules are antibiotics used for treating a variety of different bacterial infections, including respiratory infections, urinary tract infections, severe acne, skin and skin structure infections, Lyme disease, and anthrax. In the United States, five companies supply generic doxycycline monohydrate capsules: Lupin, Gavis, Endo International plc, Allergan, Inc., and Sun Pharmaceutical Industries Ltd. All five companies offer the 100 mg strength, but only four companies, including Lupin and Gavis, offer the 50 mg and 75 mg strengths. Gavis is a recent entrant into the market, having just launched its product in late July 2015.

9. Generic mesalamine ER capsules are used to treat ulcerative colitis. Valeant Pharmaceuticals markets Apriso, the branded version of the product, which is available in a 375 mg formulation. No generic version of mesalamine ER capsules is currently available in the United States. Lupin and Gavis/Novel are developing generic mesalamine ER capsules and are two of a

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limited number of suppliers capable of entering the market in the near future.

V. ENTRY CONDITIONS

10. Entry into the relevant markets described in Paragraphs 6 and 7 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisitions. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisitions.

VI. EFFECTS OF THE ACQUISITIONS

11. The effects of the Acquisitions, if consummated, may be to substantially lessen competition 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 Lupin and Gavis/Novel and reducing the number of independent significant competitors in the market for generic doxycycline monohydrate capsules, thereby increasing the likelihood that: (1) Lupin would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Lupin and Gavis/Novel in the market for generic mesalamine ER capsules, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of one of the generic mesalamine ER capsule products in development; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the

Order to Maintain Assets

substantial additional price competition that would have resulted from an additional supplier of these products.

VII. VIOLATIONS CHARGED

12. The Acquisitions described in Paragraph 5 constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisitions described in Paragraph 5, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighteenth day of February, 2016 issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Lupin Ltd. (“Lupin”) of the voting securities of Respondent Gavis Pharmaceuticals LLC (“Gavis”) and Respondent Novel Laboratories, Inc. (“Novel”), collectively “Respondents,” and Respondents having been furnished thereafter with a copy of 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 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

Order to Maintain Assets

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 to accept the executed Consent Agreement 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 Maintain Assets:

1. Respondent Lupin is a corporation organized, existing, and doing business under and by virtue of the laws of India with its principal executive offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 200 051, India, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, MD 21202.
2. Respondent Gavis is a limited liability corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.
3. Respondent Novel is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

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4. The Commission has jurisdiction over 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 to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Lupin” means: Lupin Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Lupin Ltd., including, but not limited to, Lupin Pharmaceuticals, Inc., Lupin Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Lupin shall include Gavis and Novel.
- B. “Gavis” means: Gavis Pharmaceuticals LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Gavis, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Novel” means: Novel Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novel Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

Order to Maintain Assets

- D. “Respondents” means Lupin, Gavis, and Novel, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- G. “Divestiture Product Business(es)” means the Business of Respondents within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondents and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondents.
- H. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph V of the Decision and Order.
- I. “Transition Period” means, for Doxycycline, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondents to cease the marketing, distribution, and sale of Doxycycline; or (ii) the date on which the Acquirer commences the marketing, distribution, and sale of a Doxycycline Product.
- J. “Orders” means the Decision and Order and this Order to Maintain Assets.

Order to Maintain Assets

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.

- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such Business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of such Divestiture Product Businesses, and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

Order to Maintain Assets

1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business, and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and

Order to Maintain Assets

6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. For the Acquirer of Doxycycline, Respondents shall:
1. for a period of twelve (12) months from the Closing Date or until the hiring of twenty (20) Doxycycline Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Doxycycline Core Employees related to the Doxycycline Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Doxycycline Core Employee Access Period;"
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondents to provide the Doxycycline Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer with the Doxycycline Employee Information related to the Doxycycline Core Employees. Failure by Respondents to provide the Doxycycline Employee Information for any Doxycycline Core Employee within the time provided herein shall extend the Doxycycline Core Employee Access Period with

Order to Maintain Assets

respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing, to Doxycycline Core Employees the opportunity to enter into employment contracts during a Doxycycline Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Doxycycline Core Employee Access Period, not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Doxycycline Core Employees related to the Doxycycline Assets acquired by that Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Doxycycline Product, or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to any Doxycycline Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Doxycycline Core Employee under the terms of that employee's

Order to Maintain Assets

employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Doxycycline Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Doxycycline Product consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Doxycycline Assets and to ensure successful execution of the pre-Acquisition plans for Doxycycline. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the assets related to the Doxycycline has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and

provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Doxycycline Core Employees in connection with the Acquisition;

5. for a period of one (1) year from the Closing Date, not directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to Doxycycline (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing

Order to Maintain Assets

Designee or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the non-solicitation requirements contained herein;

provided further, however, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications, or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

- E. During the Transition Period, with respect to each Doxycycline Product that is marketed or sold in the United States before the Closing Date, Respondents, in consultation with the Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Doxycycline Products by the Acquirer is not delayed or impaired by the Respondents;
 2. designate employees of Respondents knowledgeable about the marketing, distribution and sale of each of the Doxycycline Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer of the Divestiture Products Business to the Acquirer;
 3. maintain and manage inventory levels of the Doxycycline Products in consideration of the marketing and distribution transition to the Acquirer;

Order to Maintain Assets

4. continue to market, distribute, and sell the Doxycycline Products;
 5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Doxycycline Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
 6. provide the Acquirer with a listing of inventory levels (week of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) on a regular basis and in a timely manner;
 7. provide the Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
 8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.
- F. Pending divestiture of the Divestiture Product Assets, Respondents shall:
1. not use, directly or indirectly, any Confidential Business Information related to the Divestiture Products Business other than as necessary to comply with the following:
 - a. the requirements of this Order;

Order to Maintain Assets

- b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
- 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed);
 - 3. not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products; and
 - 4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access, or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain

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Assets is issued by the Commission, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.

- H. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondents' personnel.
- I. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability, and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting,

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deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission hereby appoints Francis J. Civile as the Monitor and approves the Monitor Agreements between Mr. Civile and Respondents.
- B. The Commission shall select the 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 a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute one or more agreement(s) that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents’ compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

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1. The Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and, with respect to the Doxycycline Assets, the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order until the earliest of: (i) date the Acquirer of the Doxycycline Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture the Doxycycline Product and is able to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents; (ii) the date the Acquirer of the Doxycycline Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the Doxycycline Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture the Doxycycline Product;

provided, however, that, with respect to the Doxycycline Product, the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

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- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The 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 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 Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable 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 gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any

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reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; *provided, however,* beginning ninety (90) days after Respondents have filed their first report pursuant to Paragraph IX.B. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture the Doxycycline Product and obtaining the ability to manufacture each Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or

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directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph IX.B. of the related Decision and Order, 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 the Orders. Respondents shall submit at the same time a copy of their report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of their efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondents to the relevant Acquirer(s), and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations;

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports

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required to be submitted by Respondent pursuant to Paragraph IX of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

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- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) 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. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed; or
- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

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The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Lupin Ltd. (“Lupin”) of the voting securities of Respondent Gavis Pharmaceuticals LLC (“Gavis”) and Respondent Novel Laboratories, Inc. (“Novel”), collectively “Respondents,” and Respondents having been furnished thereafter with a copy of 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 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 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 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 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 consideration of public comments, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, 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”):

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1. Respondent Lupin is a corporation organized, existing and doing business under and by virtue of the laws of India with its principal executive offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 200 051, India, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, MD 21202.
2. Respondent Gavis is a limited liability corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.
3. Respondent Novel is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.
4. The Commission has jurisdiction over 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 the Order, the following definitions shall apply:

- A. “Lupin” means: Lupin Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates, in each case controlled by Lupin Ltd., including, but not limited to, Lupin Pharmaceuticals, Inc., Lupin Inc., and the respective directors, officers, employees, agents, representatives,

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successors, and assigns of each. After the Acquisition, Lupin shall include Gavis and Novel.

- B. “Gavis” means: Gavis Pharmaceuticals LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Gavis Pharmaceuticals LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Novel” means: Novel Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Novel Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. “Respondents” means Lupin, Gavis, and Novel, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer(s)” means the following:
1. G&W Laboratories, Inc. (“G&W”); or
 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- G. “Acquisition” means Respondent Lupin’s proposed acquisition of one hundred percent (100%) of the voting securities of Respondent Gavis and Respondent Novel, respectively, pursuant to a *Purchase and Sale Agreement* dated July 23, 2015, to effect the Acquisition by and among VGS Pharma, LLC, Mendham Holdings, LLC, Veerappan Subramanian

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and Govindammal Subramanian, Anu Radha Subramanian, and Lupin Inc., that was submitted to the Commission.

- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- K. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

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- L. “Categorized Assets” means the following assets and rights of the specified Respondent(s) (as that Respondent(s) is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Orders in this matter and as are maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;
 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 3. all Product Approvals related to the specified Divestiture Product;
 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 5. all Product Marketing Materials related to the specified Divestiture Product;
 6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
 7. all Website(s) related exclusively to the specified Divestiture Product;
 8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
 9. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all of the NDC Numbers

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related to the specified Divestiture Product, and rights, to the extent permitted by Law:

- a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
- b. to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
- c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);
- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
- e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is

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necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

- f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
10. all Product Development Reports related to the specified Divestiture Product;
 11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
 12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
 13. for each specified Divestiture Product that has been marketed or sold by the Respondents prior to the Closing Date,
 - a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each

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High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

- b. for each month for each High Volume Account for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by the Respondent (as that Respondent is identified in the definition of the Divestiture Product) net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and
 - c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: average wholesale price; wholesale acquisition cost; and price to Medicare;
14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
 15. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;

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16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the specified Divestiture Product;
17. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
19. all of the Respondent's books, records, and files directly related to the foregoing;

Provided, however, that "Categorized Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

Provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to

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the specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- M. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- N. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- O. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.

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- P. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records, or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- Q. “Contract Manufacture” means the following:
1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
 2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent and in the identical dosage strength, formulation, and presentation as a Contract Manufacture Product on behalf of an Acquirer;

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3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

R. “Contract Manufacture Product” means:

1. Doxycycline; and
2. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients, or packaging materials (including, without limitation, drug vials);

Provided, however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent’s agreement to Contract Manufacture.

S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the

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extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

Provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- U. “Divestiture Product(s)” means the following, individually and collectively:
1. Doxycycline; and
 2. Mesalamine.
- V. “Divestiture Product Assets” means the following, individually and collectively:
1. Doxycycline Assets; and
 2. Mesalamine Assets.
- W. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondents:
1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the Geographic Territory;

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2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the Geographic Territory; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the Geographic Territory; and

Provided, however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

- X. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- Y. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph VI of this Order.

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- Z. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- AA. “Doxycycline” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondents Gavis and/or Novel pursuant to ANDA No. 204446, and any supplements, amendments, or revisions to this ANDA.
- BB. “Doxycycline Assets” means all rights, title, and interest in and to all assets related to the Business of Respondents Gavis and Novel within the Geographic Territory related to Doxycycline, to the extent legally transferable, including, without limitation, the Categorized Assets related to Doxycycline.
- CC. “Doxycycline Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to the Contract Manufacture Product.
- DD. “Doxycycline Divestiture Agreements” means the following:
1. *Asset Purchase Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., dated as of February 3, 2016;
 2. *Supply Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., to be executed on or before the Closing Date; and
 3. all amendments, exhibits, attachments, agreements, and schedules attached thereto and submitted with the foregoing listed agreements.

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The Doxycycline Divestiture Agreements are contained in Non-Public Appendix I. The Doxycycline Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- EE. "Doxycycline Employee Information" means the following, for each Doxycycline Core Employee, as and to the extent permitted by Law:
1. a complete and accurate list containing the name of each Doxycycline Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
 2. with respect to each such employee, the following information:
 - a. direct contact information including, but not limited to, a telephone number;
 - b. the date of hire and effective service date;
 - c. job title or position held;
 - d. a specific description of the employee's responsibilities related to Doxycycline; *provided, however*, in lieu of this description, the specified Respondent may provide the employee's most recent performance appraisal;
 - e. the base salary or current wages;
 - f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;

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- g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
 - i. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- FF. "Drug Master File(s)" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- GG. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- HH. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- II. "G&W" means G&W Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, NJ 07080.
- JJ. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be, among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following

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dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

- KK. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- LL. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- MM. “Mesalamine” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondents Gavis and/or Novel pursuant to ANDA No. 205841, and any supplements, amendments, or revisions to this ANDA.
- NN. “Mesalamine Assets” means all rights, title, and interest in and to all assets related to the Business of Respondents Gavis and Novel within the Geographic Territory related to Mesalamine, to the extent legally transferable, including, without limitation, the Categorized Assets related to Mesalamine.
- OO. “Mesalamine Divestiture Agreement” means the *ANDA Purchase Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., dated as of February 2, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Mesalamine Divestiture Agreement is contained in Non-Public Appendix II. The Mesalamine Divestiture Agreement that has been approved by the

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Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective is a Remedial Agreement.

- PP. "Monitor" means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.
- QQ. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- RR. "Orders" means this Decision and Order and the related Order to Maintain Assets.
- SS. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.
- TT. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- UU. "Patent(s)" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- VV. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or

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Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.

- WW. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- XX. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.
- YY. “Product Contracts” means all contracts or agreements:
1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
 2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in

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connection with the manufacture of the specified Divestiture Product;

3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;

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12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

Provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondents shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- ZZ. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data,

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market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

AAA. "Product Development Reports" means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted

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with the FDA relating to the Application(s) related to the specified Divestiture Product;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged

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to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
 16. analytical methods development records related to the specified Divestiture Product;
 17. manufacturing batch records related to the specified Divestiture Product;
 18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- BBB. “Product Intellectual Property” means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, or controlled by Respondents Gavis and Novel as of the Closing Date:
1. Patents;
 2. Product Copyrights;
 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or

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proprietary technical, business, research, Development, and other information; and

4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing;

Provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Lupin”, “Gavis” or “Novel”, or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof; or general registered images or symbols by which Lupin, Gavis, or Novel can be identified or defined.

CCC. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Respondents Gavis and Novel as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are

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related to a Divestiture Product and that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and

2. in those instances in which the Respondent (i) is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

DDD. “Product Manufacturing Employees” means all salaried employees of a Respondent who have directly participated in the planning, design, implementation, or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

EEE. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings,

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standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

FFF. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

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- GGG. “Product Research and Development Employees” means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.
- HHH. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.
- III. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- JJJ. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- KKK. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to this Order.
- LLL. “Remedial Agreement(s)” means the following:
1. any agreement between a Respondent(s) and G&W that is specifically referenced and attached to this

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Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of G&W that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between a Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or

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rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

MMM. “Retained Product” means any Product(s) other than a Divestiture Product.

NNN. “Right of Reference or Use” means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

OOO. “Supply Cost” means a cost not to exceed the Respondent’s (as that Respondent is identified in the definition of the respective Divestiture Product) average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.

PPP. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information

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and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;

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- b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

QQQ. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

RRR. “Third Party(ies)” means any non-governmental Person other than the following: the Respondents; or the Acquirer of particular assets or rights pursuant to this Order.

SSS. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Doxycycline Assets and grant the related Divestiture Product License,

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absolutely and in good faith, to G&W pursuant to, and in accordance with, the Doxycycline Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of G&W or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Doxycycline Assets is incorporated by reference into this Order and made a part hereof;

Provided, however, that if Respondents have divested the Doxycycline Assets to G&W prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that G&W is not an acceptable purchaser of the Doxycycline Assets, then Respondents shall immediately rescind the transaction with G&W, in whole or in part, as directed by the Commission, and shall divest the Doxycycline Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

Provided further, however, that if Respondents have divested the Doxycycline Assets to G&W prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Doxycycline Assets to G&W (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

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- B. For the Acquirer of a Contract Manufacture Product, Respondents shall provide, or cause to be provided, to that Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- C. For the Acquirer of a Contract Manufacture Product, Respondents shall:
1. upon reasonable written notice and request from the Acquirer to Respondents, Contract

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Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondents, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) from Persons other than Respondents;

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving that Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

Provided, however, that a Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with that Respondent's

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responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however*, that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by a Respondent to the Acquirer in an agreement to Contract Manufacture;

Provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s), unless Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a

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Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondents use or have used to source their own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;
8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and
9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondents and training, at the written request of the Acquirer and

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at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.C.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) three (3) years after the Closing Date.

- D. Respondents shall require, as a condition of continued employment post-divestiture of the Doxycycline Assets, that each employee that has had responsibilities related to the marketing or sales of Doxycycline within the one (1) year period prior to the Closing Date and each employee that has

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responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Doxycycline Product, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Doxycycline Product as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- E. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to Doxycycline by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondents' personnel.
- F. For the Acquirer of a Contract Manufacture Product, Respondents shall:

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1. for a period of twelve (12) months after the Closing Date or until the hiring of twenty (20) Doxycycline Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Doxycycline Core Employees. This period is hereinafter referred to as the “Doxycycline Core Employee Access Period;”
2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondents to provide the Doxycycline Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Doxycycline Employee Information related to the Doxycycline Core Employees. Failure by Respondents to provide the Doxycycline Employee Information for any Doxycycline Core Employee within the time provided herein shall extend the Doxycycline Core Employee Access Period with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to Doxycycline Core Employees the opportunity to enter into employment contracts during a Doxycycline Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use;
3. during the Doxycycline Core Employee Access Period(s), not interfere with the hiring or

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employing by that Acquirer or its Manufacturing Designee of the Doxycycline Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Divestiture Product, or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to any Doxycycline Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

Provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Doxycycline Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Doxycycline Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market Doxycycline consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Doxycycline Assets and to ensure successful execution of the pre-Acquisition plans for Doxycycline. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the Doxycycline Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

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provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Doxycycline Core Employees in connection with the Acquisition; and

5. for a period of one (1) year after the Closing Date, not directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to Doxycycline (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

Provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the non-solicitation requirements contained herein;

Provided further, however, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications, or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

- G. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product

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Intellectual Property related to Doxycycline, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of Doxycycline anywhere in the world for the purposes of marketing, sale, or offer for sale within the United States of America; or (ii) the import, export, use, supply, distribution, sale, or offer for sale of Doxycycline, into, from, or within, the United States of America.

- H. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of Doxycycline anywhere in the world of Doxycycline for the purposes of marketing, sale, or offer for sale within the United States of America; or (ii) the import, export, use, supply, distribution, or sale, or offer for sale of Doxycycline, into, from, or within, the United States of America of Doxycycline:
1. cooperate with the relevant Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to Doxycycline;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation related to Doxycycline; and
 3. permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work

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product in the possession of Respondent's outside counsel related to Doxycycline.

III.**IT IS FURTHER ORDERED** that:

- A. Not later than immediately prior to the Acquisition Date, Respondents Gavis and Novel shall divest the Mesalamine Assets and grant the related Divestiture Product License, absolutely and in good faith, to G&W pursuant to, and in accordance with, the Mesalamine Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of G&W or to reduce any obligations of Respondents under such agreement), and such agreement, if it becomes a Remedial Agreement related to the Mesalamine Assets, is incorporated by reference into this Order and made a part hereof.
- B. Respondent Lupin may not complete the Acquisition until after Respondents Gavis and Novel have divested the Mesalamine Assets to a Commission-approved Acquirer pursuant to a Remedial Agreement.

IV.**IT IS FURTHER ORDERED** that:

- A. Prior to the Closing Date for each respective Divestiture Product, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by the Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.
- B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are

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necessary to permit Respondents to divest the Divestiture Product Assets required to be divested pursuant to this Order to an Acquirer, and to permit the Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

Provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

C. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by the Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such

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Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 6. not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.
- D. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the Acquirer:

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1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
 2. Respondents shall not sell, transfer, encumber or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.
- E. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer:
1. under any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a

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Product, or that claims a device relating to the use thereof;

2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to a Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer within the United States of America. Respondents shall also covenant to the Acquirer(s) that as a condition of any assignment or license from Respondent(s) to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer(s) or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale of such Divestiture Product(s) within the United States of America; or (ii) import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer into, from, or within the United States of America. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from a

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Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- F. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
 2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.

IT IS FURTHER ORDERED that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Commission hereby appoints Francis J. Civile as the Monitor and approves the Monitor Agreements between Mr. Civile and Respondents.
- B. Not later than one (1) day after the appointment of the Monitor, Respondents shall execute one or more

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agreement(s) that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

- C. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. The Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and, with respect to the Doxycycline Assets, the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order until the earliest of: (i) the date the Acquirer of the Doxycycline Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Doxycycline Product and is able to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer of the Doxycycline Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the Doxycycline Product; or (iii) the date of written notification from staff of the

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Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Doxycycline Product;

Provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders.
- E. The 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 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 Monitor's duties and responsibilities.
- F. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the

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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 gross negligence, willful or wanton acts, or bad faith by the Monitor.

- G. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph IX.B, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture the Doxycycline Product and obtaining the ability to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- H. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- I. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and

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information received in connection with the performance of the Monitor's duties.

- J. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor.
- K. In the event a substitute Monitor is required, the Commission shall select the Monitor, 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 proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the substitute Monitor all the rights and powers necessary to permit the substitute Monitor to monitor Respondent's compliance with the terms of this Order, the Order to Maintain Assets, and the Remedial Agreements in a manner consistent with the purposes of this Order.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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VI.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the 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, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be

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deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute an agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books,

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records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture 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 Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable 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 and 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 Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture 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

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may set. The Divestiture 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 Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant

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provisions of this Order or the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

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VII.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

Provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph VII pursuant to an appropriate confidentiality order, agreement, or arrangement;

Provided further, however, that pursuant to this Paragraph VII, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order

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to protect the confidentiality of such information during any adjudication.

VIII.**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondents, all as soon as reasonably practicable.
- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

Decision and Order

- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

IX.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II, III, and IV, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondents to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

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2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

X.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- D. any proposed dissolution of a Respondent;
- E. any proposed acquisition, merger or consolidation of a Respondent; or
- F. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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

Decision and Order

documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on April 20, 2026.

By the Commission.

NON-PUBLIC APPENDIX I**DOXYCLINE DIVESTITURE AGREEMENTS****NON-PUBLIC APPENDIX II****MESALAMINE DIVESTITURE AGREEMENT**

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Lupin Ltd. (“Lupin”) and Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. (collectively “Gavis”) that is designed to remedy the anticompetitive effects resulting from Lupin’s acquisition of Gavis. Under the terms of the proposed Consent Agreement, the parties are required to divest all of Gavis’s rights and assets related to generic doxycycline monohydrate capsules and generic mesalamine extended release (“ER”) capsules to G&W Laboratories (“G&W”).

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

Pursuant to Purchase and Sale Agreements dated July 23, 2015, Lupin plans to acquire Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. for approximately \$850 million (the “Proposed Acquisitions”). Gavis and Novel are related companies. Novel researches, develops and manufactures generic pharmaceutical products, which Gavis markets and sells. The Commission alleges in its Complaint that the Proposed Acquisitions, if consummated, 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 lessening current competition in the market for generic doxycycline monohydrate capsules and future competition in the market for generic mesalamine ER capsules in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisitions.

Analysis to Aid Public Comment

The Products and Structure of the Markets

The Proposed Acquisitions would reduce the number of current suppliers in the market for generic doxycycline monohydrate capsules and reduce the number of future suppliers in the market for generic mesalamine ER capsules.

Generic doxycycline is an antibiotic used for treating a variety of different bacterial infections, including respiratory infections, urinary tract infections, severe acne, skin and skin structure infections, Lyme disease, and anthrax. Generic doxycycline monohydrate is available in four strengths: 50 mg, 75 mg, 100 mg, and 150 mg. Gavis and Lupin both market three of the four strengths, 50 mg, 75 mg, and 100 mg. Both Lupin and Gavis are recent entrants into the generic doxycycline monohydrate market; Lupin launched its product in March 2014, while Gavis launched its product at the end of July 2015. Endo International plc, Allergan, Inc., and Sun Pharmaceutical Industries Ltd. also offer generic doxycycline monohydrate products in the United States. All five companies offer the 100 mg strength, but only four companies offer the 50 mg and 75 mg strengths.

Mesalamine ER capsules are used to treat ulcerative colitis. Valeant Pharmaceuticals markets Apriso, the branded version of the product, which is available in a 375 mg formulation. No generic version of mesalamine ER capsules is currently available in the United States. Lupin and Gavis are developing generic mesalamine ER capsules products, and are two of a limited number of suppliers capable of entering the market in the near future.

Entry

Entry into the two relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisitions. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

Analysis to Aid Public Comment

Effects

The Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating current competition between Lupin and Gavis in the market for generic doxycycline monohydrate capsules. Market participants characterize generic doxycycline monohydrate capsules as commodity products. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisitions would combine two of only four companies offering the 50 mg and 75 mg strengths of generic doxycycline monohydrate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating future generic competition that would otherwise have occurred in the mesalamine ER capsule market if Lupin and Gavis remained independent. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisitions due to the elimination of an additional independent entrant in the market for generic mesalamine ER. Customers and competitors expect that the price of this pharmaceutical product will decrease with new entry by Lupin and Gavis. Thus, absent a remedy, the Proposed Acquisitions will likely cause U.S. consumers to pay significantly higher prices for generic mesalamine ER.

The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisitions in the markets at issue by requiring Gavis to divest all its rights and assets relating to doxycycline monohydrate capsules and mesalamine ER to G&W. Founded in 1919, G&W is a privately held, family-owned, generic pharmaceutical company. G&W develops, manufactures, sells, and distributes generic pharmaceuticals and over-the-counter products within the United States.

Analysis to Aid Public Comment

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisitions. If the Commission determines that G&W is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to G&W and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed D&O requires that Lupin supply G&W with generic doxycycline monohydrate capsules for two years while Lupin transfers the manufacturing technology to G&W's facility. To ensure the success of the generic doxycycline monohydrate capsules divestiture, the proposed D&O requires Lupin to provide transitional services to assist G&W in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Gavis, and advice and training from knowledgeable employees of the parties.

To assist G&W with completing the regulatory work and setting up and validating the manufacturing for the generic mesalamine ER product, G&W will enter into a consulting agreement with Gavis's current CEO, Dr. Veerappan Subramanian, who will not be employed by Lupin post-transaction. Dr. Subramanian is the founder of Gavis and has previously served as the chief scientist for the company. He has been involved with the development and manufacturing of the generic mesalamine ER product since the company started the formulation. G&W will also inherit Gavis's ongoing patent litigation related to mesalamine ER. G&W intends to retain Gavis's current counsel to continue the litigation.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to

Analysis to Aid Public Comment

constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

HIKMA PHARMACEUTICALS PLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4568; File No. 151 0198**Complaint, February 26, 2016 – Decision, May 4, 2016*

This consent order addresses the \$2 billion acquisition by Hikma Pharmaceuticals PLC of certain assets of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsules market, and future competition in the market for generic flecainide tablets in the United States. The consent order requires Hikma to divest all of its rights and assets related to 5 mg, 10 mg, and 20 mg generic prednisone tablets and to generic lithium carbonate capsules to Renaissance Acquisition Holdings LLC, and to divest all marketing rights and ownership interests in generic flecainide tablets to Unimark Remedies Ltd.

Participants

For the *Commission: Jacqueline K. Mendel and David von Nirschl.*

For the *Respondent: Jonathan Gleklen, Peter Levitas and John Rackson, Arnold & Porter LLP.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Hikma Pharmaceuticals PLC (“Respondent” or “Hikma”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, “Roxane”) from Boehringer Ingelheim Corporation (“Boehringer”) in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the

Complaint

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the 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 Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales, with its corporate office and principal place of business located at 13 Hanover Square, London, W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: Corporate Secretary, West-Ward Pharmaceuticals, 401 Industrial Way W, Eatontown, NJ 07724.

2. The Respondent 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 affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

3. Pursuant to the terms of a Stock Purchase Agreement dated July 28, 2015, as amended, among Respondent, Eurohealth (U.S.A.), Inc., and Boehringer, Respondent intends to acquire 100% of the issued and outstanding shares of Roxane for approximately \$2 billion in cash and stock (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

4. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

Complaint

- a. 5 mg, 10 mg, and 20 mg generic prednisone tablets;
- b. generic lithium carbonate capsules; and
- c. generic flecainide tablets.

5. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

6. Generic prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. In addition to its use as an anti-inflammatory medication, prednisone is used as an immunosuppressant medication. In the United States, five firms supply 5 mg, 10 mg, and 20 mg generic prednisone tablets: Hikma; Roxane; Allergan, Inc.; Jubilant Cadista Pharmaceuticals, Inc.; and Endo International plc. The Acquisition would therefore reduce the number of suppliers of 5 mg, 10 mg, and 20 mg generic prednisone tablets from five to four.

7. Generic lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. Lithium therapy reduces the frequency of manic episodes and diminishes the intensity of episodes when they occur. There are four firms that currently supply generic lithium carbonate capsules: Hikma, Roxane, Glenmark Pharmaceuticals Ltd., and Camber Pharmaceuticals Inc. The Acquisition would therefore reduce the number of suppliers of generic lithium carbonate capsules from four to three.

8. Generic flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. Four firms currently market generic flecainide tablets: Roxane, Amneal Pharmaceuticals, ANI Pharmaceuticals, Inc. and Citron Pharma. Hikma owns the U.S. marketing rights to a generic flecainide product that has been filed with the U.S. Food and Drug

Complaint

Administration (“FDA”). Upon approval, Hikma likely would be the fifth supplier of generic flecainide tablets. The Acquisition would therefore eliminate the entry of a fifth independent market participant.

V. ENTRY CONDITIONS

9. Entry into each of the relevant markets described in Paragraphs 6 through 8 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

10. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or 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 Hikma and Roxane and reducing the number of independent significant competitors in the markets for generic 5 mg, 10 mg, and 20 mg prednisone tablets and generic lithium capsules, thereby increasing the likelihood that: (1) Hikma would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Hikma and Roxane in the market for generic flecainide tablets, thereby (1) increasing the likelihood that the combined

Order to Maintain Assets

entity would forgo or delay the launch of the generic flecainide tablets to which Hikma owns the U.S. marketing rights; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

VII. VIOLATIONS CHARGED

11. The Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

12. The Acquisition described in Paragraph 3, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of February, 2016, issues its Complaint against said Respondent.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Hikma Pharmaceuticals PLC (“Hikma” or “Respondent”) of the voting securities of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. from their ultimate parent entity, C.H. Boehringer Sohn AG & Co. KG, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if

Order to Maintain Assets

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 waives and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement 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 Maintain Assets:

1. Respondent Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales with its principal executive offices located at 13 Hanover Square, London W1S 1HW, United Kingdom and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o West-Ward Pharmaceuticals Corp., 401 Industrial Way West, Eatontown, NJ 07724.
2. Roxane Laboratories, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Nevada with its executive offices and principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.

Order to Maintain Assets

3. Boehringer Ingelheim Roxane, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.
4. C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany with its principal executive offices located at Binger Strasse 173, Ingelheim am Rhein, Germany 55216.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, 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 and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Hikma” or “Respondent” means: Hikma Pharmaceuticals PLC; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Hikma Pharmaceuticals PLC (including, without limitation, West-Ward Pharmaceuticals Corp. and Eurohealth (U.S.A.), Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Hikma shall include Roxane Laboratories, Inc., and Boehringer Ingelheim Roxane, Inc.
- B. “Commission” means the Federal Trade Commission.

Order to Maintain Assets

- C. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- D. “Divestiture Product Business(es)” means the Business of Respondent within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- E. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- F. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the relevant Acquirer directs the Respondent to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the relevant Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).
- G. “Orders” means the Decision and Order and this Order to Maintain Assets.

Order to Maintain Assets

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondent shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.

- B. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondent's responsibilities shall include, but are not limited to, the following:

Order to Maintain Assets

- a. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
- b. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
- c. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
- d. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondent prior to the date the Respondent entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
- e. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and

Order to Maintain Assets

- f. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
1. for a period of twelve (12) months from the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the

Order to Maintain Assets

time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

Order to Maintain Assets

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and
5. for a period of one (1) year from the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing

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Designee or who independently applies for employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that this Paragraph does not require nor shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent.

- E. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date, Respondent, in consultation with the relevant Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Divestiture Products by the Acquirer is not delayed or impaired by the Respondent;
 2. designate employees of Respondent knowledgeable about the marketing, distribution, and sale related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting

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in the transfer of the Business related to the Divestiture Products to the Acquirer;

3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
 4. continue to market, distribute, and sell the Divestiture Products;
 5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
 6. provide the Acquirer with a listing of inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) on a regular basis and in a timely manner;
 7. provide the Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
 8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.
- F. Pending divestiture of the Divestiture Product Assets, Respondent shall:

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1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed);
3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; and
4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and

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- b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- H. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgment program. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.
- I. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and

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competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Monitor, 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 a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

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- D. If an Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. The Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets, and the transfer and delivery of the related Product Manufacturing Technology, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Divestiture Product and able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

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provided, however, that, with respect to each Divestiture Product, the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets.

Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders.

- F. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable 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

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such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

- H. Respondent shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VII.B. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.
- I. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and

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information received in connection with the performance of the Monitor's duties.

- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VII.B. of the related Decision and Order, Respondent 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 the Orders. Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

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- B. a detailed description of the timing for the completion of such obligations.

Provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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

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Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) 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. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

Decision and Order

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Hikma Pharmaceuticals PLC (“Hikma” or “Respondent”) of the voting securities of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. from their ultimate parent entity, C.H. Boehringer Sohn AG & Co. KG, and Respondent having been furnished thereafter with a copy of 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 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 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 consideration of public comments, and having modified the Decision and Order in certain respects, 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”):

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1. Respondent Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales with its principal executive offices located at 13 Hanover Square, London W1S 1HW, United Kingdom, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o West-Ward Pharmaceuticals Corp., 401 Industrial Way West, Eatontown, NJ 07724.
2. Roxane Laboratories, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Nevada with its executive offices and principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.
3. Boehringer Ingelheim Roxane, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.
4. C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany with its principal executive offices located at Binger Strasse 173, Ingelheim am Rhein, Germany 55216.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**I.**

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

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- A. “Hikma” or “Respondent” means: Hikma Pharmaceuticals PLC; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Hikma Pharmaceuticals PLC (including, without limitation, West-Ward Pharmaceuticals Corp. and Eurohealth (U.S.A.), Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Hikma shall include Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer(s)” means the following:
- a. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 - b. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- D. “Acquisition” means Respondent Hikma’s acquisition of fifty percent (50%) or more of the voting securities of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. Respondent entered a *Stock Agreement and Plan of Merger* dated July 28, 2015, among Hikma Pharmaceuticals PLC, Eurohealth (U.S.A.), Inc., and Boehringer Ingelheim Corporation, that was submitted to the Commission.

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- E. “Acquisition Date” means the date on which the Acquisition is consummated.
- F. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- G. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- H. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- I. “Categorized Assets” means the following assets and rights of the Respondent, as such assets and rights are in existence as of the date the Respondent signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in

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accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:

1. all rights to all of the Applications related to the specified Divestiture Product;
2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
3. all Product Approvals related to the specified Divestiture Product;
4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;
8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments

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for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

- b. to prohibit Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
- c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by the Respondent);
- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
- e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and
- f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the

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Respondent prior to such notification(s) being disseminated to the customer(s);

10. all Product Development Reports related to the specified Divestiture Product;
11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
13. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date:
 - a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis, including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

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- b. for each High Volume Account, for each month, for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by the Respondent net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and
 - c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: average wholesale price; wholesale acquisition cost; and price to Medicare;
14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
15. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;
16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process,

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and finished goods related to the specified Divestiture Product;

17. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
19. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to the Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the

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Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- J. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- K. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- L. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- M. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:

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1. information relating to the Respondent's general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records, or books of the Respondent that is provided to an Acquirer by the Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- N. "Contract Manufacture" means the following:
1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
 2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or
 3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

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- O. “Contract Manufacture Product(s)” means:
1. Lithium Products;
 2. Prednisone Products; and
 3. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials);
- provided, however,* that with the consent of the Acquirer of the specified Product, the Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent’s agreement to Contract Manufacture.
- P. “Development” means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- Q. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s

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employees' labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- R. "Divestiture Product(s)" means the following, individually and collectively:
1. Lithium Products;
 2. Flecainide Products; and
 3. Prednisone Products.
- S. "Divestiture Product Assets" means the following, individually and collectively:
1. Lithium Product Assets;
 2. Flecainide Product Assets; and
 3. Prednisone Product Assets.
- T. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.
- U. "Divestiture Product License" means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent:

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1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the Geographic Territory; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the Geographic Territory;

provided, however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by the Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

- V. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

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- W. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- X. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- Y. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. “Geographic Territory” means the United States of America, including all of its territories and possessions, unless otherwise specified.
- AA. “Flecainide Product(s)” means all Products in Development by Unimark that are orally administered tablets containing, as an active pharmaceutical ingredient, flecainide acetate, at the following strengths: 50mg, 100mg, and 150mg.
- BB. “Flecainide Product Assets” means all rights to develop, manufacture, market, commercialize, sell, or distribute the Flecainide Products.
- CC. “Flecainide Product Divestiture Agreements” means:
1. *Flecainide Agreement* between Unimark Remedies Limited and West-Ward Pharmaceuticals Corp., dated as of December 13, 2015;
 2. *Termination of Share Subscription and Shareholder’s Agreement* from Hikma Pharmaceuticals LLC to Unimark Remedies Limited, dated as of March 10, 2016;

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3. *Termination of Product Development, Manufacturing, Supply and Marketing Agreement* from West-Ward Pharmaceutical Corporation to Unimark Remedies, dated as of March 10, 2016;
4. *Share Purchase Agreement* amongst Royal Star Limited and Hikma Pharmaceuticals LLC and Unimark Remedies Limited, dated as of March 10, 2016; and
5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Flecainide Product Divestiture Agreements are contained in Non-Public Appendix II. The Flecainide Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- DD. "Government Entity" means any Federal, state, local, or non-U.S. government; or any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.
- EE. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be, among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end

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of the last quarter following the Acquisition or the Closing Date.

- FF. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- GG. “Lithium Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Hikma pursuant to the following Applications:
1. ANDA No. 76243; and
 2. ANDA No. 78763;
- and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, lithium carbonate, at the following strengths: 150mg, 300mg, and 600mg.
- HH. “Lithium Product Assets” means all rights, title, and interest in and to all assets related to the Business of Hikma within the Geographic Territory related to each of the Lithium Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Lithium Products.
- II. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- JJ. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- KK. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by

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the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

- LL. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- MM. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- NN. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- OO. “Ownership Interest” means any and all rights, title, and interest, present or contingent, to hold any of the following:
1. any voting or non-voting stock, share capital, equity, other interests, or beneficial ownership in a specified entity; or
 2. any notes or options convertible into any voting or non-voting stock in a specified entity.
- PP. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- QQ. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or

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Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.

RR. “Prednisone/Lithium Product Divestiture Agreements” means the following:

1. *Asset Purchase Agreement* between Hikma Pharmaceuticals PLC and Delcor Asset Corporation, dated as of February 16, 2016;
2. *Supply Agreement (Prednisone)* between Hikma Pharmaceuticals LLC and Delcor Asset Corporation, attached to the *Asset Purchase Agreement* and to be executed on or before the Closing Date;
3. *Supply Agreement (Lithium Carbonate)* between West-Ward Pharmaceuticals Corp. and Delcor Asset Corporation, attached to the *Asset Purchase Agreement* and to be executed on or before the Closing Date; and
4. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Prednisone/Lithium Product Divestiture Agreements are contained in Non-Public Appendix I. The Prednisone/Lithium Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

SS. “Prednisone Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Hikma pursuant to the following Applications:

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1. ANDA No. 80292;
2. ANDA No. 88832; and
3. ANDA No. 83677;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, prednisone, at the following strengths: 5mg, 10mg, and 20mg.

- TT. “Prednisone Product Assets” means all rights, title, and interest in and to all assets related to the Business of Hikma within the Geographic Territory related to each of the Prednisone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Prednisone Products.
- UU. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- VV. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

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WW. “Product Contracts” means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of the Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process

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including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;

8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

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XX. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of the Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control

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data; and all correspondence with the FDA or any other Agency.

YY. “Product Development Reports” means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;

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10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;

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19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- ZZ. “Product Employee Information” means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:
1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
 2. with respect to each such employee, the following information:
 - a. direct contact information for the employee, including telephone number;
 - b. the date of hire and effective service date;
 - c. job title or position held;
 - d. a specific description of the employee’s responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the Respondent may provide the employee’s most recent performance appraisal;
 - e. the base salary or current wages;
 - f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year, and current target or guaranteed bonus, if any;

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- g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- AAA. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, or controlled by the Respondent as of the Closing Date:
- 1. Patents;
 - 2. Product Copyrights;
 - 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
 - 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing;
- provided, however,* that "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Hikma" or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or

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companies owned or controlled by the Respondent or the related corporate logos thereof; or general registered images or symbols by which Hikma can be identified or defined.

BBB. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Respondent as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
2. in those instances in which (i) the Respondent is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to

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the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

CCC. “Product Manufacturing Employees” means all salaried employees of the Respondent who have directly participated in the planning, design, implementation, or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

DDD. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and

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3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.
- EEE. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.
- FFF. "Product Research and Development Employees" means all salaried employees of the Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.
- GGG. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.

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- HHH. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.
- III. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- JJJ. “Proposed Acquirer” means a Person proposed by the Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to this Order.
- KKK. “Remedial Agreement(s)” means the following:
1. any agreement between the Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
 2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that is

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specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

LLL. "Renaissance" means Renaissance Acquisition Holdings LLC, a corporation organized, existing, and doing business under and by virtue of the laws of Canada with its principal executive offices located at 370 Chemin Chambly, Suite 300, Longueuil (Québec) J4H3Z6. Renaissance Acquisition Holdings includes Renaissance Pharma, Inc., Prestium Pharma, Inc., DPT Labs, Confab, and Delcor Asset Corporation.

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- MMM. “Retained Product(s)” means any Product(s) other than a Divestiture Product.
- NNN. “Right of Reference or Use” means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials); (ii) Product Development Reports; or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.
- OOO. “Supply Cost” means a cost not to exceed the Respondent’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- PPP. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*:
1. designating employees of the Respondent knowledgeable about the Product Manufacturing

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Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;

2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such

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intellectual property related to the specified Divestiture Product.

- QQQ. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.
- RRR. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; or the Acquirer of particular assets or rights pursuant to this Order.
- SSS. “Unimark” means Unimark Remedies Limited, a corporation organized, existing, and doing business under and by virtue of the laws of India with its registered office at Enterprise Centre, 1st Floor, Off Nehru Road, Vile Parle (East), Mumbai, India, Pin-400 099. Unimark includes its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Unimark Remedies Limited. The ultimate parent entity of Unimark is Mr. Mehul J. Parekh, Managing Director, Unimark Remedies Limited.
- TTT. “Unimark Product Development Agreement” means the *Product Development, Manufacturing, Supply and Marketing Agreement* by and between Unimark Remedies Limited and West-Ward Pharmaceutical Corporation dated as of May 3, 2011. The Unimark Product Development Agreement is contained in Non-Public Appendix II.
- UUU. “Unimark Supplementary Agreement” means the *Supplementary Agreement* between Unimark Remedies Limited and West-Ward Pharmaceutical Corporation, dated as of February 18, 2016. The Unimark Supplementary Agreement relates and refers to the Unimark Product Development Agreement. The Unimark Supplementary Agreement is contained in Non-Public Appendix II.

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VVV. “Unimark Share Subscription and Shareholders’ Agreement” means the *Share Subscription and Shareholders’ Agreement* between Hikma Pharmaceuticals LLC and Unimark Remedies Limited and The Promoters of Unimark Remedies Limited, dated as of April 13, 2011. The Unimark Share Subscription and Shareholders’ Agreement is contained in Non-Public Appendix II.

WWW. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.**IT IS FURTHER ORDERED** that:

A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Prednisone Product Assets and the Lithium Product Assets and grant the related Divestiture Product Licenses, absolutely and in good faith, to Renaissance pursuant to, and in accordance with, the Prednisone/Lithium Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Renaissance or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Prednisone Product Assets and the Lithium Product Assets is incorporated by reference into this Order and made a part hereof;

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provided, however, that if Respondent has divested the Prednisone Product Assets and the Lithium Product Assets to Renaissance prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Renaissance is not an acceptable purchaser of either the Prednisone Product Assets or the Lithium Product Assets, then Respondent shall immediately rescind the transaction with Renaissance, in whole or in part, as directed by the Commission, and shall divest the Prednisone Product Assets and the Lithium Product Assets (as applicable) within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondent has divested the Prednisone Product Assets and the Lithium Product Assets to Renaissance prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Prednisone Product Assets and the Lithium Product Assets to Renaissance (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than thirty (30) days after the Acquisition Date, Respondent shall:
1. divest, absolutely and in good faith, all of its Ownership Interest in Unimark to Mr. Mehul J. Parekh (founder and Managing Director of Unimark), Mr. Parekh's spouse, Mr. Parekh's

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daughter, as designated in the *Share Purchase Agreement* (as identified in the definition of Flecainide Divestiture Agreements), or to any company designated by Mr. Parekh that is wholly owned jointly or singly by the aforementioned three individuals, pursuant to the *Share Purchase Agreement*;

2. divest all rights it may have in the Flecainide Product Assets to Unimark pursuant to the *Flecainide Agreement* (as identified in the definition of Flecainide Divestiture Agreements); *provided, however*, if Respondent has divested the Flecainide Product Assets to Unimark prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Flecainide Product Assets to Unimark (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order;
3. terminate the Unimark Product Development Agreement pursuant to the *Termination of Product Development, Manufacturing, Supply and Marketing Agreement* (as identified in the definition of Flecainide Divestiture Agreements); *provided, however*, Respondent may enter into the Unimark Supplementary Agreement under which agreement any rights Respondent may have to the Flecainide Products pursuant to the Unimark Product Development Agreement shall not survive; and
4. terminate the Unimark Share Subscription and Shareholder's Agreement pursuant to the

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Termination of Share Subscription and Shareholder's Agreement (as identified in the definition of Flecainide Divestiture Agreements) which shall, *inter alia*, terminate any rights Respondent may have to:

- a. acquire any additional Ownership Interest in Unimark;
- b. exercise dominion or control over, or otherwise influence, the management, direction, or supervision of the business of Unimark, including, but not limited to, any participation in the formulation, determination, or direction of any business decisions of Unimark; *provided, however*, this provision shall not apply to the Business related to those Products developed with Unimark under the Unimark Product Development Agreement prior to the termination of this agreement other than the Flecainide Products;
- c. nominate members of, or in any other way seek or obtain representation on, the Board of Directors of Unimark;
- d. have any of the Respondent's directors, officers, or employees serve simultaneously as an officer or director of Unimark;
- e. access any confidential, proprietary, or other non-public information from Unimark relating to the research, Development, manufacture, distribution, sale, or marketing of the Flecainide Products; or
- f. access any confidential, proprietary, or other non-public information from Unimark relating to the research, Development, manufacture, distribution, sale, or marketing of any Products owned by Unimark other than such information

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as is related to a Product that Hikma is distributing, marketing, selling, or developing pursuant to a specific agreement directly related to the Product with Unimark;

provided, however, this shall not be construed to prohibit the Respondent from: (i) seeking information from Unimark as a part of normal due diligence for the purposes of negotiating a transaction with Unimark; or (ii) seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between the Respondent and Unimark in accordance with the procedures of the forum before which the dispute is pending. With respect to any such discovery, the Respondent shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any Person(s) not necessary to the resolution of such dispute.

- C. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide each Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.
- D. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Divestiture Product Assets to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

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provided, however, Respondent may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product Assets has executed all such agreements directly with each of the relevant Third Parties.

- E. Respondent shall:
1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
 2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
 4. not use, directly or indirectly, any such Confidential Business Information related to the

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Business of the Divestiture Products other than as necessary to comply with the following:

- a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.
- F. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall provide, or cause to be provided, to that Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and

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2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to the Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.

- G. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
 1. upon reasonable written notice and request from the Acquirer to Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug

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product independently of Respondent, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the Respondent from Persons other than the Respondent;

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondent to the Acquirer in an agreement to Contract Manufacture;

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provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
4. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly

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to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. in the event Respondent becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;
8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and
9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to

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satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.G.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Closing Date.

- H. Respondent shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the

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Respondent (other than as necessary to comply with the requirements of this Order).

- I. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.
- J. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
 1. for a period of twelve (12) months after the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"

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2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would

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affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to any Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the Divestiture Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

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5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications, or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent.

- K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer:
 1. Respondent shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;

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- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.
- L. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer:
1. under any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
 2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

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if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America. The Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- M. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by

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that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America.

- N. For any patent infringement suit filed prior to the Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America, the Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
 2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent

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that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondent's outside counsel related to that Divestiture Product.
- O. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
 2. to create a viable and effective competitor that is independent of the Respondent in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.

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- B. The Commission shall select the Monitor, 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 a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If a Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. The Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets, and the transfer and delivery of the related Product Manufacturing

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Technology, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders.

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- F. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable 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 gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining

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the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

- I. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may

Decision and Order

appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*I*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*I*), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to § 5(*I*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

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- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused

Decision and Order

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 Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable 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 and 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 Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture 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 Divestiture 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 necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining

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monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality

Decision and Order

agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including,

Decision and Order

without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that the Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph V, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific

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reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.

- D. For each Divestiture Product that is a Contract Manufacture Product, Respondent shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondent, all as soon as reasonably practicable.
- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

Decision and Order

VII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C., II.D., II.E.1, II.E.2., II.E.3, II.F., II.G., II.H., II.I., II.J., and II.K., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 - 2. a detailed description of the timing for the completion of such obligations.

- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

Decision and Order

VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger, or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

Decision and Order

X.

IT IS FURTHER ORDERED that this Order shall terminate on May 4, 2026.

By the Commission.

NON-PUBLIC APPENDIX I

**AGREEMENTS RELATED TO THE DIVESTITURES
OF THE LITHIUM PRODUCTS AND THE PREDNISONE
PRODUCTS**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

III. NON-PUBLIC APPENDIX II

IV.

**AGREEMENTS RELATED TO THE DIVESTITURE
OF THE FLECAINIDE PRODUCTS**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Hikma Pharmaceuticals PLC (“Hikma”) that is designed to remedy the anticompetitive effects resulting from Hikma’s acquisition of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, “Roxane”) from Boehringer Ingelheim Corporation (“BI”). Under the terms of the proposed Consent Agreement, Hikma must divest all of its rights and assets related to 5 mg, 10 mg, and 20 mg generic prednisone tablets and to generic lithium carbonate capsules to Renaissance Acquisition Holdings LLC (“Renaissance”), and to divest all marketing rights and ownership interests in generic flecainide tablets to Unimark Remedies Ltd (“Unimark”).

The Commission has placed the proposed Consent Agreement on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed consent Agreement or make final the Decision and Order (“Order”).

Pursuant to a Stock Purchase Agreement dated July 28, 2015, Hikma proposed to acquire 100% of the issued and outstanding shares of Roxane for approximately \$2.65 billion. On February 10, 2016, the purchase price was reduced to approximately \$2 billion (the “Proposed Acquisition”). The Commission alleges in its Complaint that the Proposed 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 Commission Act, as amended, 15 U.S.C. §45, by lessening current competition in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsules market, and future competition in the market for generic flecainide tablets in the United States. The proposed Consent Agreement will remedy

Analysis to Aid Public Comment

the alleged violations by preserving the competition that the Proposed Acquisition would otherwise eliminate.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of current suppliers in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and for generic lithium carbonate capsules, and reduce the number of future suppliers in the market for generic flecainide tablets.

Prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. Prednisone is also prescribed as an immunosuppressant medication. Generic prednisone is available in six tablet strengths: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, and 50 mg. Hikma and Roxane both market three of the six tablet strengths: 5 mg, 10 mg, and 20 mg. In addition to Hikma and Roxane, Endo International plc, Allergan, Inc., and Jubilant Cadista Pharmaceuticals, Inc. also offer 5 mg, 10 mg, and 20 mg generic prednisone tablets in the United States.

Lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. Lithium therapy reduces the frequency of manic episodes and diminishes the intensity of episodes when they occur. In addition to Hikma and Roxane, two other firms currently supply generic lithium carbonate capsules in the United States: Glenmark Pharmaceuticals Ltd. and Camber Pharmaceuticals Inc.

Flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. Four firms currently market generic flecainide tablets: Roxane, Amneal Pharmaceuticals, ANI Pharmaceuticals, Inc., and Citron Pharma. Hikma owns the U.S. marketing rights to a generic flecainide in development at Unimark Remedies Ltd. Hikma is one of few suppliers that can enter the United States market in the near future.

Analysis to Aid Public Comment

Entry

Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Hikma and Roxane in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsule market. Market participants characterize both generic prednisone tablets and generic lithium carbonate capsules as commodity products, and prices are typically inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisition would combine two of five companies offering the 5 mg, 10 mg, and 20 mg strengths of generic prednisone tablets, and two of four firms offering generic lithium carbonate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisition likely would harm consumers by eliminating future generic competition that would otherwise have occurred in the generic flecainide market if Hikma and Roxane remained independent. The Proposed Acquisition would likely harm competition by eliminating an additional independent entrant in the market for generic flecainide. Customers view the price of this pharmaceutical product as less competitive than it would be in a market with more participants, including Hikma. Thus, absent a remedy, the Proposed Acquisition would likely cause U.S. consumers to pay significantly higher prices for generic flecainide tablets.

Analysis to Aid Public Comment

The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition by requiring Hikma to divest all its rights and assets relating to 5 mg, 10 mg, and 20 mg generic prednisone and those relating to generic lithium carbonate capsules to Renaissance. Established in 2010 and based in Newtown, Pennsylvania, Renaissance is a privately held pharmaceutical company that manufactures and markets both generic and branded prescription drugs in the United States. In addition, the proposed Consent Agreement requires Hikma to return its rights to market generic flecainide tablets in the United States to Unimark, along with its equity interest in Unimark.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Renaissance is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Hikma to unwind the sale of rights to Renaissance and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee should the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Hikma supply Renaissance with 5 mg, 10 mg, and 20 mg generic prednisone tablets and with generic lithium carbonate capsules for eighteen months while Hikma transfers the manufacturing technology to Renaissance's facility. The proposed Order also requires Hikma to provide a back-up supply of active pharmaceutical ingredient for generic prednisone tablets should the need for it arise. To ensure the success of these divestitures, the proposed Order requires Hikma to provide transitional services to assist Renaissance in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Hikma, and advice and training from knowledgeable employees of the

Analysis to Aid Public Comment

parties. In addition, to ensure that Hikma complies with the terms of the Consent Agreement, the Commission has appointed Owen Richards of Quantic Regulatory Services, LLC as the Interim Monitor.

To remedy competitive concerns raised by the acquisition in the market for generic flecainide tablets, the proposed Order requires Hikma to divest its approximately 23% ownership interest in Unimark and to return to Unimark all rights it has to commercialize generic flecainide tablets in the United States. Unimark has selected another firm, Bion Pharma, of Princeton, New Jersey, to market generic flecainide tablets in the United States upon the product's approval by the FDA.

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

Complaint

IN THE MATTER OF

**STAPLES, INC.
AND
OFFICE DEPOT, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTIONS 7 AND 11 OF THE CLAYTON ACT

*Docket No. 9367; File No. 151 0065
Complaint, December 7, 2015 – Decision, May 18, 2016*

This consent order addresses the \$6.3 billion acquisition by Staples, Inc. of certain assets of Office Depot, Inc. The complaint alleges that the merger of the two largest competitors in the market would substantially reduce competition in the sale and distribution of consumable office supplies to large business-to-business customers in the United States. The final order dismisses the Complaint, on the ground that Respondents have abandoned their proposed merger and Staples has withdrawn its Hart-Scott-Rodino Notification and Report Form.

Participants

For the *Commission: Helder Agostinho, Kimberley Biagioli, Krisha Cerilli, Maria DiMoscato, Stephanie Greco, Kelly Home, Amanda Lewis, Chuck Loughlin, David Owyang, Rohan Pai, Angel Prado, Ryan Quillian, Haidee Schwartz, Joshua Smith, Stelios Xenakis, and Robert Zuver.*

For the *Respondents: Steven Bernstein, Steven Newborn, Jeffrey Perry, and Diane Sullivan, Weil, Gotshal & Manges LLP; Andrew Lacy and Matthew Reilly, Simpson Thacher & Bartlett LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by the virtue of the authority vested in it by the FTC Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondents Staples, Inc. (“Staples”) and Office Depot, Inc. (“Office Depot”) have executed a merger agreement in violation of Section 5 of the FTC

Complaint

Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC 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 pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I.**NATURE OF THE CASE**

1. Respondents are—by a wide margin—the two largest vendors of consumable office supplies to large “business-to-business” (“B-to-B”) customers (i.e., business customers buying for their own end-use) in the United States.

2. Staples’ and Office Depot’s own documents state that they are the only participants in a “two player” national market. Respondents are the best options for most large B-to-B customers—and the only meaningful options for some large B-to-B customers—particularly those with facilities in multiple regions of the country. And they are each other’s closest competitors for such customers. As Staples explained at an internal Leadership Summit, “There are only two real choices for customers,” Staples and Office Depot. Office Depot similarly made clear to a customer that “[o]n a national scale, Office Depot’s competition is Staples.”

3. Direct head-to-head competition between Staples and Office Depot yields substantial benefits to large B-to-B customers in the form of lower prices and better service. If consummated, the merger of Staples and Office Depot (the “Merger”) would eliminate that competition. Office Depot acknowledged this in April 2015—two months after the Merger was announced—encouraging a large B-to-B customer to accept its “best and final” offer promptly, stating, “If and when [Staples’] purchase of Office Depot is approved, Staples will have no reason to make this offer.”

Complaint

4. By eliminating direct competition between Staples and Office Depot, the Merger threatens significant harm to a wide range of large B-to-B customers.

5. Office supplies vendors, such as Respondents, sell and distribute consumable office supplies (*e.g.*, pens, staplers, notepads, folders, and copy paper) to all manner of businesses across the United States. Employees of these businesses use consumable office supplies in connection with their jobs. As a result, businesses depend on vendors to provide consistent and reliable delivery of consumable office supplies so that their employees have the products they need to work productively and on a cost-effective basis.

6. Large B-to-B customers typically require an office supplies vendor with experience and a strong reputation for providing consumable office supplies to large B-to-B customers. These requirements are especially important for customers seeking delivery on a multi-regional or national basis. Many large B-to-B customers require that their office supplies vendor provide a broad range of national-brand and private-label products, flexible and reliable delivery (including desktop delivery), high levels of customer service, customizable product catalogs, detailed utilization reporting, and sophisticated information technology (“IT”) interfaces for procurement and billing. Moreover, large B-to-B customers require those features and services to be part of the transaction, along with consumable office supplies at competitive prices.

7. Large businesses typically purchase consumable office supplies pursuant to contracts awarded through requests for proposal (“RFPs”), auctions, or bilateral negotiations. Respondents generally compete head-to-head in such proceedings. They are often the two finalists in RFPs or other contests because they can obtain the lowest cost of goods from office supplies manufacturers and they possess similar networks of distribution centers, salesforces, and other services and features, such as strong reputations and experience, high levels of customer service, sophisticated IT, and product utilization monitoring and tracking. Large B-to-B customers often use those similar offerings to play one Respondent off the other to obtain

Complaint

lower pricing, other financial incentives, better service, and improved contract terms. Indeed, Staples and Office Depot frequently lower prices, increase discounts, and offer other financial incentives to take business away from each other, and to avoid losing business to each other.

8. Many large B-to-B customers contract with a single office supplies vendor for consumable office supplies. Doing so allows these customers to consolidate their purchases and leverage the bigger purchasing volume to negotiate lower prices and higher discounts, rebates, or other pricing concessions. In addition, contracting with a single office supplies vendor allows large businesses to track and monitor usage of office supplies through one vendor, rather than several different vendors, thereby lowering their costs and improving operational efficiency. Using a single office supplies vendor also provides large B-to-B customers with a single point of contact for problems or concerns, a single IT interface for ordering, and a single payee for administrative purposes. These features are important to many large B-to-B customers because they enhance efficiency, ease of use, and administration, thereby lowering their costs of doing business.

9. For large B-to-B customers with locations across the United States or in multiple regions of the country, using a single office supplies vendor generally means choosing an office supplies vendor with national or multi-regional distribution capabilities. Staples and Office Depot are the only two office supplies vendors that can provide on their own the low prices, nationwide distribution, and combination of services and features that many large B-to-B customers require.

10. Once a large B-to-B customer contracts with an office supplies vendor, it attempts to ensure that the employees responsible for purchasing consumable office supplies purchase under the contract with its chosen office supplies vendor. Maximizing spend with its contracted office supplies vendor often allows a large B-to-B customer to earn the highest volume-based discounts, rebates, or other pricing incentives. It also minimizes the inefficiency of having to pay invoices from multiple vendors and accommodate multiple deliveries.

Complaint

11. Other supply options have significant disadvantages for large B-to-B customers.

12. Local or regional vendors (including but not limited to W.B. Mason), local or regional consortia, and ad hoc region-by-region networks of suppliers have higher costs and thus higher prices, limited geographic footprints, and/or logistical and coordination challenges for large B-to-B customers. Because of these disadvantages, these other supply options have relatively small shares of sales to large B-to-B customers.

13. The Merger would combine the office supplies vendors that are—by far—the two top choices for a significant number of large B-to-B customers. It would eliminate beneficial competition between the two largest, most significant, and most attractive alternatives for many large B-to-B customers.

14. The Merger also would create a firm with a dominant share of the relevant market and significantly increase market concentration. Post-Merger, Staples would control more than 70% of the relevant market. The next-largest competitor would possess less than 5% of the relevant market. Under the 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (“Merger Guidelines”), a post-merger market-concentration level above 2,500 points, as measured by the Herfindahl-Hirschman Index (“HHI”), and an increase in market concentration of more than 200 points renders a merger presumptively unlawful. Post-Merger market concentration would be more than 4900, and would increase HHIs in an already concentrated market by well over 200 points. Thus, the Merger is presumptively unlawful.

15. Other office supplies vendors, including but not limited to Amazon Business, regional vendors such as W.B. Mason, distribution consortia, and vendors of adjacent products, such as janitorial/sanitation products or breakroom supplies, cannot meaningfully constrain a post-Merger Staples. As a result, Staples could charge higher prices and would have a diminished incentive to maintain or improve quality for large B-to-B customers if it were allowed to acquire Office Depot.

Complaint

16. Similarly, manufacturers of “core” consumable office products, such as pens, folders, and notepads, generally do not sell core office supplies directly to large B-to-B customers, particularly in the quantities that such customers would want. They generally sell to wholesalers or vendors such as Respondents. Nor would it be practicable for large B-to-B customers to buy office supplies from a large number of manufacturers. Wholesalers do not generally sell consumable office supplies directly to large B-to-B customers. Rather, they generally sell to office supplies vendors, which then resell those products to large B-to-B customers.

17. Finally, buying at retail, whether from brick-and-mortar or online retailers, including Amazon Business, generally would be more expensive for large B-to-B customers than purchasing from an office supplies vendor, and generally would not provide the full combination of other benefits important to large B-to-B customers, such as desktop delivery, order tracking, electronic ordering, flexible payment terms, negotiated pricing, and consistency of product selection and availability.

18. Respondents cannot show that new entry or expansion by existing vendors would be timely, likely, or sufficient to counteract the anticompetitive effects of the Merger. Significant barriers to entry into office supplies distribution to large B-to-B customers—particularly national and multi-regional customers—exist, making entry or expansion difficult and incapable of constraining the merged entity.

19. Respondents cannot show cognizable efficiencies that would offset the likely and substantial competitive harm from the Merger.

II.

BACKGROUND

A.

Jurisdiction

20. Respondents, and each of their relevant operating entities and parent entities are, and at all relevant times have been,

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engaged in commerce or in activities affecting “commerce” as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

21. The Merger constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

B. Respondents

22. Respondent Staples is a publicly traded corporation organized under the laws of Delaware with headquarters in Framingham, Massachusetts. In fiscal year 2014, Staples generated \$22.5 billion in sales, with 54.8% of that coming from office supplies. Staples operates three business segments: North American Stores & Online, North American Commercial, and International Operations. In fiscal year 2014, 36.8% of Staples’ total sales came from the North American Commercial segment. Staples is the country’s largest vendor of consumable office supplies to B-to-B customers.

23. Respondent Office Depot is a publicly traded corporation organized under the laws of Delaware with headquarters in Boca Raton, Florida. In fiscal year 2014, Office Depot had \$16.1 billion in revenue, with 47.2% of that coming from sales of office supplies. Office Depot operates through three divisions: North American Retail Division, North American Business Solutions Division, and International Division. In fiscal year 2014, 37.4% of Office Depot’s sales came from the North American Business Solutions Division. Office Depot is the country’s second-largest vendor of consumable office supplies to B-to-B customers.

C. The Merger

24. On February 4, 2015, Staples and Office Depot entered into an Agreement and Plan of Merger (“Merger Agreement”), pursuant to which each share of Office Depot stock would be converted into the right to receive \$7.25 in cash, plus approximately 0.2 shares of Staples’ common stock. As of the market’s close on February 3, 2015, these terms of the Merger

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Agreement equated to a value of Office Depot of \$6.3 billion. Either party may terminate the Merger Agreement if it is not consummated by February 4, 2016.

III.
RELEVANT MARKET

25. The relevant market is the sale and distribution of consumable office supplies to large business-to business customers in the United States. Large B-to-B customers are particularly vulnerable to the proposed Merger because many have nationwide or multi-regional operations and require an office supplies vendor that can provide low pricing, high levels of service, and delivery across all of their operations. For such customers, Staples and Office Depot are the two best options.

A.
Relevant Product Market

26. Consumable office supplies consist of an assortment of office supplies, such as pens, paper clips, notepads, and copy paper, that are used and replenished frequently. It is appropriate to evaluate the Merger's likely effects through an analysis of the assortment of consumable office supplies because each of the products in the assortment is offered under similar competitive conditions. Thus, grouping the hundreds of individual consumable office supplies into an assortment for analytical convenience enables the efficient evaluation of competitive effects with no loss of analytic power.

27. B-to-B customers buy consumable office supplies for their own end-use (i.e., for their employees to use in the course of performing their job duties), rather than for resale.

28. Consumable office supplies do not include ink and toner for printers and copiers. Many B-to-B customers, particularly large B-to-B customers, buy ink and toner directly from ink and toner manufacturers, or as part of a package of "managed print services," in which vendors bundle ink and toner sales with leases of copier and printers, repair services, and/or copy and printer maintenance services. As a result, large B-to-B customers often

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purchase ink and toner from different vendors, under different contracts, than those from which they purchase consumable office supplies.

29. Consumable office supplies do not include other office-related products, such as janitorial or break-room products. Janitorial or break-room products are sold under substantially different competitive conditions than consumable offices supplies.

30. Large B-to-B customers include, but are not limited to, those that buy \$1 million annually of consumable office supplies for their own end-use.

31. The sale and distribution of consumable office supplies to large B-to-B customers, many of whom have multi-regional or national operations, entails the warehousing, sale, and distribution of a wide range of such office supplies, along with high levels of customer service and value-added services.

32. The sale and distribution of consumable office supplies to large B-to-B customers is distinct from the sale and distribution of consumable office supplies to other customers, including individual consumers or small- and medium-sized businesses. Large B-to-B customers generally require, and the sale and distribution of consumable office supplies to large B-to-B customers is distinguished by, a number of key attributes, including but not limited to:

- a. Procurement Processes: Large B-to-B customers generally procure consumable office supplies on contracts awarded through formal RFPs, auctions, or direct negotiations, often obtaining lower prices than other customers.
- b. National or Multi-Regional Distribution: Many large B-to-B customers have operations in multiple regions of the United States. As a result, to increase efficiency and reduce transaction costs, large B-to-B customers often require a single vendor with a broad geographic footprint that can distribute consumable office supplies to all their locations in multiple regions of the country.

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- c. Next-Day Desktop Delivery: Many large B-to-B customers require next-day and desktop delivery—that is, delivery to one or more desks or drop-off points within an office building—to reduce storage costs.
- d. High Levels of Service: Large B-to-B customers require that their office supplies vendors provide high levels of customer service, including dedicated account representatives and/or customer service representatives to address any customer concerns or issues in a timely manner.
- e. Valued-Added Services: Large B-to-B customers often require detailed utilization reporting to allow them to track and monitor on a regular basis their employees' uses of and needs for office products. They also often require the creation of customizable product catalogs to encourage their employees to order and use products for which they have already negotiated the lowest prices.
- f. Sophisticated IT Systems: Large B-to-B customers generally require their office supplies vendor to have sophisticated IT capabilities that interface directly with their e-procurement and billing systems.
- g. Reputation and Financial Stability: Large B-to-B customers generally require an office supplies vendor with experience and a strong reputation for supplying large B-to-B customers with office supplies, as well as financial stability.

33. Respondents recognize the particular needs of large B-to-B customers and tailor their products and services to meet those needs. Both Respondents categorize B-to-B customers by size, with groups of employees dedicated to serving different groups of customers.

34. Thus, the sale and distribution of consumable office supplies to large B-to-B customers is the relevant product market in which to analyze the Merger's likely effects.

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B.**Relevant Geographic Market**

35. Respondents compete for the sale and distribution of consumable office supplies across the United States. Many large B-to-B customers operate nationally or in multiple regions of the country. Accordingly, it is appropriate to analyze the competitive effects of the Merger in the United States.

36. Respondents' own documents acknowledge the existence of a national market for the sale and distribution of consumable office supplies to large B-to-B customers, referring to themselves as the only two players in a "national market."

37. Respondents compete to provide the sale and distribution of consumable office supplies to large B-to-B customers through their respective networks of warehouses and distribution centers located around United States.

38. Many large businesses have a number of locations dispersed nationwide or across multiple regions of the United States. A substantial number of large B-to-B customers choose a single office supplies vendor with a geographically dispersed network of distribution centers to serve their facilities. These customers do so because consolidating their purchases with a single vendor gives them the ability to get lower prices, or increased discounts, rebates or other pricing incentives, from that vendor. In addition, choosing a single nationwide office supplies vendor provides large B-to-B customers with centralized and consistent services and terms across their facilities, including: (1) centralized contracting, (2) a single point of contact, (3) a single reporting/auditing function, (4) a single IT interface for users, and (5) ease of administration of the distribution contract.

39. Additionally, many large B-to-B customers enter into contracts for nationwide distribution, with nationwide pricing terms, and consider the vendor's ability to provide nationwide distribution and service in the selection process. Many large B-to-B customers with operations in multiple regions of the country, as opposed to nationwide, similarly want one vendor that can provide consistent pricing, service, and delivery across all their

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locations, and therefore often require a vendor with national capabilities.

40. Therefore, for consumable office supplies sold and distributed to large B-to-B customers, the United States is the relevant geographic market.

V.

**MARKET STRUCTURE AND THE MERGER'S
PRESUMPTIVE ILLEGALITY**

41. Staples and Office Depot are by far the two largest vendors of consumable office supplies to large B-to-B customers. When large B-to-B customers issue RFPs for the sale and distribution of office supplies, Staples and Office Depot (including the legacy OfficeMax business) are usually the two finalists for the business. In fact, Respondents are often the only two companies that submit a proposal to supply a broad range of consumable office supplies on a nationwide basis.

42. The Merger Guidelines and courts measure concentration using the Herfindahl-Hirschman Index (“HHI”). The HHI is calculated by totaling the squares of the market shares of every firm in the relevant market. Under the Merger Guidelines, a merger is presumed likely to create or enhance market power—and is presumptively illegal—when the post-merger HHI exceeds 2,500 and the merger increases the HHI by more than 200 points.

43. The market for the sale and distribution of consumable office supplies to large B-to-B customers is highly concentrated, and the parties control the majority of sales. Post-Merger, the market would be substantially more highly concentrated than it is today. Post-Merger, Staples would control more than 70% of this relevant market. The next largest competitor would possess less than 5% of the relevant market. The Merger would result in a post-Merger HHI of well over 2500, and an increase in concentration of well over 200 points. Post-Merger market concentration would be more than 4900, and would increase HHIs in an already concentrated market by well over 200 points. Thus, the Merger would result in concentration above the amount necessary to establish a presumption of competitive harm.

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44. The Merger is presumptively unlawful under relevant case law and the Merger Guidelines.

VI.
ANTICOMPETITIVE EFFECTS:

**The Merger Would Eliminate Vital Head-To-Head
Competition Between Staples And Office Depot**

45. Respondents are each other's closest competitors. They are the two largest vendors of consumable office supplies to large B-to-B customers in the United States. The scale and capabilities of Staples and Office Depot are similarly matched, and are much larger and more robust than those of the next-largest vendor of consumable office supplies to large B-to-B customers (a regional office supplies vendor, W.B. Mason).

46. Staples' and Office Depot's size allows them to obtain products from manufacturers at lower prices than other vendors generally can. Both also offer a collection of distribution services that no other vendor of consumable office supplies can match: a national footprint with an extensive array of warehouses and distribution centers located across the country; correspondingly large salesforces; product breadth and depth, including private-label products; a single point of contact across all of a customer's locations; a single user interface that connects to a customer's procurement and billing systems; and other significant value-added offerings, such as order tracking, utilization reporting, and customizable catalogs.

47. Respondents acknowledge that they are each other's closest competitors. One of Office Depot's own documents indicates that "[o]n a national scale, Office Depot's competition is Staples." Staples refers to itself as operating in a "2 player national market" and notes that "[t]here are only two real choices for customers."

48. Respondents are often the first and second choices for large B-to-B customers of consumable office supplies. Respondents predominantly win large B-to-B customers from, and lose large B-to-B customers to, each other.

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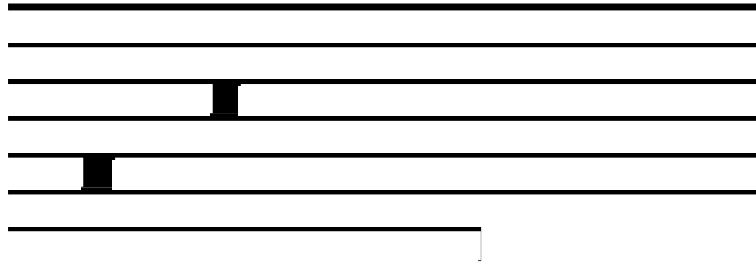
49. Respondents compete aggressively with each other on price and non-price terms to win and retain the business of large B-to-B customers. Staples and Office Depot frequently must compete with each other by lowering prices, increasing discounts or rebates, and providing significant cash incentives to win or keep large B-to-B customer accounts.

50. Large B-to-B customers benefit from the competition between Respondents. Among other things, that competition enables customers to pit Staples and Office Depot against each other to obtain lower prices and better contract terms. Large B-to-B customers switch, or threaten to switch, their business from Staples to Office Depot, and vice versa, to obtain better prices, discounts, cash incentives, and other beneficial terms.

51. The following are examples of direct price competition between Staples and Office Depot for large B-to-B customers:

- In November 2014, Office Depot offered a [REDACTED] payment [REDACTED] to secure the business of [REDACTED]. It lost out to Staples, who offered [REDACTED].
- In March 2014, [REDACTED], a Fortune 500 company, informed its current supplier, Office Depot, that it was putting its business out for bid. [REDACTED] and Office Depot discussed the fact that [REDACTED].
- In late 2013, [REDACTED] a Fortune 100 company, decided to benchmark Staples' prices against Office Depot's prices. To avoid losing [REDACTED] business to Office Depot, [REDACTED].
- In the fall of 2013, [REDACTED] a Fortune 100 company, informed Office Depot that it was switching its business to Staples unless [REDACTED]. An internal Office Depot email explains that [REDACTED].

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- In 2013, with its contract with Staples expiring, [REDACTED] a Fortune 500 company, informed Staples that it was considering Office Depot and OfficeMax as potential suppliers. Staples [REDACTED] to keep the business.
- In the fall of 2012, [REDACTED], a Fortune 100 healthcare services provider, ran a reverse auction for office products. Although Staples was the incumbent, [REDACTED] was prepared to switch to Office Depot if there was not [REDACTED]. To keep the business, Staples [REDACTED].

52. The Merger would eliminate this intense head-to-head price competition for large B-to-B customers. Post-Merger, Staples would face less meaningful competition than it does today. Consequently, Staples will not need to compete as aggressively on price to win the business of many large B-to-B customers, and it will be able to price at higher levels.

53. Staples and Office Depot also compete aggressively on non-price terms to win large B-to-B customers by offering high-quality services. Respondents currently risk losing business to each other if large B-to-B customers perceive one Respondent's service as inferior or lacking. After the Merger, Staples would face substantially less competition for large B-to-B customers, and would have less incentive to improve, or even maintain, its current level of service to win or keep business.

54. Retail stores and internet websites directed at retail consumers are not viable alternatives for most large B-to-B customers. Such retailers cannot provide the level of pricing or

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service that office supplies vendors such as Respondents provide and that large B-to-B customers require.

55. Wholesale suppliers of office supplies are not meaningful alternatives for most large B-to-B customers because wholesalers generally sell only for resale, not to businesses for their own use. Even when wholesalers work with independent vendors to distribute to customers, those wholesaler-vendor partnerships cannot provide the level of pricing or service that office supplies vendors like Respondents provide and that large B-to-B customers require.

56. Manufacturers of consumable office supplies are not a viable distribution option for most large B-to-B customers' consumable office supplies needs. Given the breadth of office supplies large B-to-B customers buy, such customers would have to purchase from a large number of different manufacturers to cover their employees' needs. Such purchasing would be highly inefficient, costly, and not practicable for most large customers. Moreover, manufacturers of consumable office supplies generally sell only in very large quantities, generally far larger than a B-to-B customer would purchase for its own use. As a result, manufacturers of consumable office supplies generally do not sell their products directly to customers buying for their own end-use and not for resale.

57. Other office supplies vendors, such as Amazon Business, regional vendors such as W.B. Mason, distribution consortia, and vendors of adjacent products, such as janitorial/sanitation products or breakroom supplies, generally have some combination of higher costs and thus higher prices, limited geographic footprints, and/or logistical and coordination challenges for large B-to-B customers. As a result, they would not meaningfully constrain Respondents' exercise of market power post-Merger.

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VII.**LACK OF COUNTERVAILING FACTORS****A.****Barriers to Entry and Expansion**

58. Respondents cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Merger.

59. A firm seeking to enter or expand in the market for the sale and distribution of consumable office supplies to large B-to-B customers, many of whom operate nationally or in multiple regions of the country, would face significant barriers to success.

60. One key obstacle to expansion by regional firms or consortia is having the geographic footprint to serve large B-to-B customers, many of which operate nationally or in multiple regions of the country. Creating a national distribution network anywhere close to that offered by Staples or Office Depot would be time and resource intensive.

61. The next-largest vendor of consumable office supplies after the Respondents, W.B. Mason, operates only in 13 states, primarily in the Northeast. _____

62. Other vendors of consumable office supplies are many years and significant capital investments away from being in a position to replace the competition that Office Depot currently provides to Staples, even assuming those other vendors were likely to expand their geographic footprints.

63. Additionally, entrants must develop sophisticated IT systems that large B-to-B customers expect, to allow customized ordering systems that interface with the customer's procurement, billing, and utilization tracking systems. Such systems are costly to develop and maintain.

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64. Large B-to-B customers also value having a relationship with an experienced sales representative that understands their particular needs. Thus, vendors seeking to enter or expand must recruit and hire a competent and experienced salesforce that can serve customers in multiple regions of the country. To hire enough sales representative to enter or expand on a sufficient scale to constrain the merged firm in multiple regions or nationally would take a significant amount of time and effort, particularly in light of non-competition and non-solicitation agreements that incumbent vendors have with their employees.

65. Entrants also must overcome reputational barriers to entry and Respondents' strong incumbency advantage. A significant percentage of RFPs are won by incumbent vendors—and often by one of the Respondents.

B.
Efficiencies

66. Respondents cannot demonstrate cognizable efficiencies that would be sufficient to rebut the strong presumption and evidence that the Merger likely would substantially lessen competition in the relevant market.

VIII.
VIOLATION

COUNT I—ILLEGAL AGREEMENT

67. The allegations of Paragraphs 1 through 66 above are incorporated by reference as though fully set forth.

68. The Merger Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II—ILLEGAL ACQUISITION

69. The allegations of Paragraphs 1 through 66 above are incorporated by reference as though fully set forth.

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70. The Merger, if consummated, may substantially lessen competition in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the tenth day of May, 2016, at 10 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary 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 Federal Trade Commission Act and the Clayton 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 you to file with the Commission an answer to this complaint on or before the fourteenth (14th) 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 Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

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Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, 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 pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Merger challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Merger is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant market, with the ability to offer such products and services as Staples and Office Depot were offering and planning to offer prior to the Merger.

Final Order

2. A prohibition against any transaction between Staples and Office Depot that combines their businesses in the relevant market, except as may be approved by the Commission.
3. A requirement that, for a period of time, Staples and Office Depot provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant markets.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore Office Depot as a viable, independent competitor in the relevant market.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this seventh day of December, 2015.

By the Commission.

ORDER DISMISSING COMPLAINT

On December 7, 2015, the Commission issued an administrative Complaint alleging that a merger agreement between Respondents Staples, Inc. and Office Depot, Inc. violates Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that if the merger were consummated, it would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, as well as Section 5 of the FTC Act. Complaint Counsel and Respondents now jointly seek dismissal of the Complaint, on the ground that Respondents

Final Order

have abandoned their proposed merger and Staples has withdrawn its Hart-Scott-Rodino Notification and Report Form.¹

The Commission has determined to dismiss the Complaint without prejudice, in light of Respondents' decision to abandon the proposed transaction and Staples' withdrawal of its Hart-Scott-Rodino Notification and Report Form. Respondents would not be able to effectuate the proposed transaction without filing new Hart-Scott-Rodino Notification and Report Forms. The Commission has therefore determined that the public interest warrants dismissal of the Complaint in this matter.² Accordingly,

IT IS ORDERED THAT the Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

1 See Joint Motion to Dismiss Complaint (May 18, 2016), at 1 & attachment.

2 See, e.g., *Sysco Corp., et al.*, Docket No. 9364, Order Dismissing Complaint (June 30, 2015), available at <https://www.ftc.gov/system/files/documents/cases/150630syscoorder.pdf>; *Verisk Analytics, Inc., et al.*, Docket No. 9363, Order Dismissing Complaint (Dec. 19, 2014), available at <https://www.ftc.gov/system/files/documents/cases/141219veriskeaglevieworder.pdf>.

Complaint

IN THE MATTER OF

HENRY SCHEIN PRACTICE SOLUTIONS, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4575; File No. 142 3161
Complaint, May 20, 2016 – Decision, May 20, 2016

This consent order addresses Henry Schein Practice Solutions, Inc.'s data security claims for its Dentrix G5 software. The complaint alleges that Henry Schein violated Section 5 of the Federal Trade Commission Act by making falsely representing that Dentrix G5 provides industry-standard encryption of patient data and helps dentists meet the security requirements of the Health Insurance Portability and Accountability Act. The consent order requires Henry Schein to notify affected customers that Dentrix G5 uses a less complex encryption algorithm to protect patient data than Advanced Encryption Standard, which is recommended as an industry standard by the National Institute of Standards and Technology. The Order also requires Henry Schein to pay \$250,000 into a fund to be administered by the Commission for such other relief (including consumer information remedies) as it determines is reasonably related to Henry Schein's practices.

Participants

For the *Commission*: *Jessica Lyon* and *Kristin Madigan*.

For the *Respondent*: *Stephen Chuk* and *Christopher Ondeck*,
Proskauer Rose, LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Henry Schein Practice Solutions, Inc., a corporation, 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 Henry Schein Practice Solutions, Inc. ("Henry Schein") is a Utah corporation with its principal office or place of business at 1220 South 630 East, American Fork, Utah 84003.

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2. Respondent manufactures, advertises, offers for sale, sells, and distributes office management software for dental practices, including but not limited to the Dentrix software described below.

3. The acts or 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.

Respondent’s Business Practices

4. Dentrix software enables dentists to perform common office tasks such as entering patient data, sending appointment reminders, processing patient payments, submitting patient insurance claims, documenting treatment planning, entering progress notes, and recording diagnostic information.

5. In the spring of 2012, Respondent introduced the Dentrix G5 software (“Dentrix G5”). Dentrix G5 incorporated a new “database engine” provided by a third-party vendor, which included new capabilities, including a form of data protection that Respondent advertised as “encryption.”

6. Dentists use Dentrix G5 to collect and store patients’ personal information. The personal information can consist of sensitive information about patients, including, in some instances:

name, address, telephone number, Social Security number, date of birth, driver’s license number, email address, web user ID and password, picture, name of insurance providers, clinical notes, prescriptions, and diagnoses.

7. As early as November 2010, the database engine vendor informed Respondent that the form of data protection used in Dentrix G5 was a proprietary algorithm that had not been tested publicly, and was less secure and more vulnerable than widely-used, industry-standard encryption algorithms, such as Advanced Encryption Standard (“AES”) encryption.

8. Prior to releasing Dentrix G5, Respondent was aware that the Department of Health and Human Services (“HHS”) directs healthcare providers, including most dentists, to guidance

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promulgated by the National Institute of Standards and Technology (“NIST”) to help them meet their regulatory obligations to protect patient data. The NIST guidance recommends AES encryption. Respondent was also aware that HHS’ Breach Notification Rule, 45 C.F.R. §§ 164.400-414, requires dentists to notify patients of certain breaches, but includes a “safe harbor” so that dentists would not have to notify patients about breached data that was encrypted consistent with NIST Special Publication 800-111.

9. Nevertheless, for a period of two years Respondent has disseminated or caused to be disseminated promotional materials and statements for the Dentrax G5 software that emphasize the product’s ability to encrypt patient data and help dentists meet regulatory obligations related to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), including but not limited to the following statements:

- a. “The database also provides new encryption capabilities that can help keep patient records safe and secure. And of course, encryption plays a key role in your efforts to stay compliant with HIPAA security standards.” (Dentrax G5 brochure).
- b. “Henry Schein is pleased to announce the release of Dentrax G5. G5 stores information in an SQL database, which . . . offers improved protection by storing your patient data in an encrypted format.” (eNewsletter Article).
- c. “The SQL database also offers improved protection by storing customer data in an encrypted format. With ever-increasing data protection regulations, Dentrax G5 provides an important line of defense for both patient and practitioner.” (eNewsletter Article).
- d. “With the release of Dentrax G5, Dentrax now stores information in an SQL database, which delivers several distinct benefits for your practice, including improved data access speed and improved data protection by storing customer data in an encrypted

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format. With medical professionals under strict regulatory obligations to protect their patients' personal health information, the new Dentrix G5 database provides an important line of defense for both patient and practitioner." (Dentrix Magazine).

- e. "Dentrix versions prior to G5 relied on the underlying Microsoft operating system and file system safeguard to protect user data. Unfortunately, these were rarely activated by default, and if practices failed to turn them on, their data were at risk to hackers. With Dentrix G5's embedded SQL database, users have the advanced protection they need without burdening them with another system to manage." (Interview in DentalTown Magazine).

10. On June 10, 2013, the United States Computer Emergency Readiness Team ("US-CERT") issued Vulnerability Note VU#900031, describing the form of data protection used in Dentrix G5 software as a "weak obfuscation algorithm." On June 16, 2013, NIST published a corresponding vulnerability alert.

11. The US-CERT Vulnerability Note stated that the database engine vendor had agreed to re-brand the data protection as "Data Camouflage" so it would not be confused with standard encryption algorithms, such as AES encryption.

12. Despite receiving notice of the US-CERT Vulnerability Note and the database vendor's decision to re-brand in June 2013, for an additional seven months, Respondent continued to disseminate marketing materials stating that Dentrix G5 "encrypts" patient data and offers "encryption."

13. The facts set forth in Paragraphs 7 and 10 would be material to dentists' purchase of Dentrix G5. An attacker who un.masks patients' sensitive personal information could subject patients to the unanticipated disclosure of personal information or use that information to commit identity theft, medical identity theft, or other harms. If dentists were aware that Dentrix G5 used a form of data protection that was more vulnerable than widely-

Complaint

used, industry standard encryption algorithms, they may have chosen to purchase another product.

14. The facts set forth in Paragraphs 7, 8, and 10 would also be material to dentists' use of Dentrax G5. For instance, without knowing that Dentrax G5 provided only minimal protection for their patients' sensitive personal information, dentists may not take other reasonable and commercially available steps to protect patients' sensitive personal information.

15. Moreover, the facts set forth in Paragraphs 7, 8, and 10 would be material to dentists responding to a data breach. For example, in the event of a breach, dentists may mistakenly believe they qualify for the encryption safe harbor under the Breach Notification Rule, and are not required to notify patients in the event of a breach. Even if a dentist does notify patients, the dentist may misinform patients about their risk of identity theft by telling them that the lost data was "encrypted."

16. Finally, in January 2014, following a series of online media reports criticizing the company's failure to amend its encryption claims, Respondent published the following statement in the Spring 2014 issue of Dentrax Magazine:

"Available only in Dentrax G5, we previously referred to this data protection as encryption. Based on further review, we believe that referring to it as a data masking technique using cryptographic technology would be more appropriate."

17. Respondent concurrently revised an array of its marketing materials replacing references to "encryption" or "encryption capabilities" with references to "a data masking technique using cryptographic technologies." Respondent also added language to many of its marketing materials warning users that this data masking technique "helps to supplement, not replace" a dentist's own security measures.

18. Aside from revising its marketing materials as described, Respondent did not take any additional steps to alert dentists who purchased Dentrax G5 prior to January 2014, that the software

Complaint

used a less complex algorithm to protect patient data than a standard encryption algorithm such as AES encryption.

Violations of Section 5**Count I****Deceptive Claims of Encryption – Industry-Standard**

19. Through the means described in Paragraphs 5, 9, and 12 Respondent has represented, directly or indirectly, expressly or by implication, that Dentrix G5 provides industry-standard encryption.

20. In truth and in fact, as described in Paragraphs 7, 10, and 11, Dentrix G5 used technology that was less secure than industry-standard encryption. Therefore, the representation set forth in Paragraph 19 was false or misleading.

Count II**Deceptive Claims of Encryption – Regulatory Obligations**

21. Through the means described in Paragraphs 5, 9, and 12 Respondent has represented, directly or indirectly, expressly or by implication, that Dentrix G5 helps dentists protect patient data, as required by HIPAA.

22. In truth and in fact, as described in Paragraphs 7, 8, 10, and 11, Dentrix G5 used technology that was not capable of helping dentists protect patient data, as required by HIPAA. Therefore, the representation set forth in Paragraph 21 was false or misleading.

23. The acts and practices of Respondent 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 twentieth day of May, 2016, has issued this complaint against Respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission” or “FTC”), 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 that 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 violations of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45 *et seq.*;

The Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), which includes: a statement by Respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the Consent Agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; 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 FTC 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 for the receipt and consideration of public comments, and having duly considered the comments filed by interested persons, now in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and enters the following Order:

1. Respondent Henry Schein Practice Solutions, Inc. (“Henry Schein”) is a Utah corporation with its principal office or place of business at 1220 South 630 East, American Fork, Utah 84003.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the

Decision and Order

Respondent, and the proceeding is in the public interest.

ORDER DEFINITIONS

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

- A. “Affected Customer(s)” means any consumer, including any dental practice, that purchased the Dentrix G5 dental office practice management software.
- B. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- C. “Clear(ly) and Conspicuous(ly)” means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 - A. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication, even if the representation requiring the disclosure is made in only one means.
 - B. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 - C. An audible disclosure, including by telephone or streaming video, must be delivered in a volume,

Decision and Order

speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

- D. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 - E. On a product label, the disclosure must be presented on the principal display panel.
 - F. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
- D. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191, 110 Stat. 1936.
- E. “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; (c) online contact information, such as an email address, instant messaging user identifier, or screen name; (d) a telephone number; (e) a Social Security number; (f) a driver’s license number or other government-issued identification number; (g) a bank account, debit card, or credit card account number; (h) a photograph; and (i) medical information about a consumer including, but not limited to, prescription information, clinical laboratory testing information, health insurance information, physician examination notes, and medical history.
- F. “Respondent” shall mean Henry Schein Practice Solutions, Inc. and its successors and assigns.

Decision and Order

I.

IT IS ORDERED that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service designed to collect or store Personal Information, in or affecting commerce, shall not misrepresent, in any matter, expressly or by implication:

- A. whether or to what extent the product or service offers industry-standard encryption;
- B. the ability of the product or service to help customers meet regulatory obligations related to privacy or security; or
- C. the extent to which a product or service maintains the privacy, security, confidentiality, and integrity of Personal Information.

II.

IT IS FURTHER ORDERED that Respondent must notify Affected Customers, Clearly and Conspicuously, that Dentrix G5 uses a less complex encryption algorithm to protect patient data than Advanced Encryption Standard (“AES”), which is recommended as an industry standard by the National Institute of Standards and Technology (“NIST”). Notification must include the following:

- A. Respondent must identify all Affected Customers who purchased Dentrix G5 prior to January 2014 (“eligible customers”).
 - 1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondent’s possession, custody, or control.

Decision and Order

2. Eligible customers include those identified at any time through the eligibility period, which runs for one (1) year after the date of service of this order.
- B. Respondent must notify all identified eligible customers by mailing each a notice:
1. The letter must be in the form shown in Attachment A.
 2. The envelope containing the letter must be in the form shown in Attachment B.
 3. The mailing of the notification letter must not include any other enclosures.
 4. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondent must use standard search methodologies such as re-checking Respondent's records and the Postal Service's National Change of Address database and re-mailing to the corrected address within eight days.
- C. Respondent must notify all eligible customers within sixty (60) days after service of this order and any eligible customers identified thereafter within thirty (30) days of their identification.
- D. Respondent must establish a toll-free telephone number and an email address dedicated to responding to inquiries about the order and must respond promptly and accurately to such inquiries.
- E. Respondent must submit reports on its notification program under penalty of perjury:
1. Respondent must submit a report, within one hundred and twenty (120) days after the date of

Decision and Order

service of this order, annually thereafter, and at the conclusion of the program summarizing its compliance to date, including: the total number of eligible customers identified, notices mailed, and notices re-mailed, the number of mailings returned as undeliverable, and efforts taken to locate the customers for whom mailings were returned and deliver them the notice, as well as the number of calls and emails received and their disposition. For customers for whom mailings were returned as undeliverable, Respondent shall make reasonable efforts to locate and notify those customers.

2. If a representative of the Commission requests any information regarding the notice program, including any of the underlying customer data, Respondent must submit it within ten (10) days of the request.

III.

IT IS FURTHER ORDERED that:

- A. Respondent must pay to the Commission \$250,000, which Respondent stipulates its undersigned counsel holds in escrow for no purpose other than payment to the Commission.
- B. Such payment must be made within eight (8) days of the effective date of this order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

IV.

IT IS FURTHER ORDERED that:

- A. All money paid to the Commission pursuant to this order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses

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for the administration of any redress fund. If a representative of the Commission decides that direct redress to Affected Customers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondent's practices alleged in the complaint. Any money not used is to be deposited to the U.S. Treasury. Respondent may, upon request, be notified whether the money has been deposited to the U.S. Treasury, but has no right to challenge any activities pursuant to this provision. No portion of any payment under this Part shall be deemed a payment of any fine, penalty, or punitive assessment.

- B. In the event of default on any obligation to make payment under this order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for ten (10) days beyond the date that payment is due, the entire amount will immediately become due and payable.
- C. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.
- D. Respondent acknowledges that its Taxpayer Identification Number, which Respondent has previously provided to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this order, in accordance with 31 U.S.C. § 7701.

V.

IT IS FURTHER ORDERED that Respondent must directly or indirectly provide sufficient customer information to enable the

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Commission to efficiently administer consumer redress to all Affected Customers. Respondent represents that it has provided this redress information to the Commission. If a representative of the Commission requests in writing any information related to redress, Respondent must provide it, in the form prescribed by the Commission representative, within fourteen (14) days.

VI.

IT IS FURTHER ORDERED that Respondent 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 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 its 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.

VII.

IT IS FURTHER ORDERED that Respondent shall deliver a copy of this order to all current and for the next five (5) years future principals, officers, directors, and managers, and to all current and future employees having managerial responsibilities with respect to the subject matter of this order. Respondent shall deliver this order to such current personnel within thirty days after service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities. For any business entity resulting from any change in structure set forth in Part VIII, delivery shall be at least ten (10) days prior to the change in structure. Respondent must secure a

Decision and Order

signed and dated statement acknowledging receipt of this order, within thirty (30) days of delivery, from all persons receiving a copy of the order pursuant to this section.

VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) 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. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must be: *In re Henry Schein Practice Solutions, Inc.*.

IX.

IT IS FURTHER ORDERED that Respondent, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, Respondent shall submit additional true and accurate written reports.

Decision and Order

X.

This order will terminate on May 20, 2036, 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

[To appear on Henry Schein Practice Solutions, Inc. letterhead]

[Date]

[Name of customer]

[Mailing address of customer
Including zip code]

SUBJECT: Important Information Regarding the Security of Patient Records
Stored in Dentrix G5

Dear Valued Customer:

Our records show you purchased Dentrix G5, which is sold by our company, Henry Schein Practice Solutions, Inc. ("HSPS"), prior to January 2014.

From early 2012 to January 2014, we advertised that Dentrix G5 "encrypts" patient data and helps dentists meet the security requirements of HIPAA, the Health Insurance Portability and Accountability Act. But according to the Federal Trade Commission, the nation's consumer protection agency, our claims were deceptive. To resolve the case, we have agreed to not make those claims in the future and to contact our customers so they can take appropriate steps to protect patient records, if necessary.

We understand that the security of your patients' records is important to you. So here's what you need to know if you use our software.

The Department of Health and Human Services ("HHS") looks to the National Institute of Standards and Technology for guidance on how healthcare providers should encrypt sensitive information. NIST recommends a method called Advanced Encryption Standard (AES) and says, "Whenever possible, AES should be used for the encryption algorithm because of its strength and speed."

This is important because if a dental practice using AES encryption experiences a data breach, it may not have to contact patients under HHS' Breach Notification Rule. Our software uses a less complex method that doesn't meet the AES encryption standard recommended by HHS and NIST. Therefore, practices relying on Dentrix G5 software alone would not qualify for the safe harbor under the Breach Notification Rule. If you experience a data breach, you may have to contact each affected patient personally – and depending on the size of the breach, you may have to notify HHS and others, too. Of course, you should obtain your own legal advice in the event of a data breach.

As of January 2014, our marketing materials state that our software "masks" data, but doesn't encrypt it. That description is more accurate and will help dentists make informed decisions about protecting their patients' data. We also strongly recommend that dentists consider multiple safeguards to secure access to patient data and work with both IT and security policy experts to create and implement a comprehensive security plan for their practice.

Decision and Order

If you have questions, please call us at [toll-free telephone number and email address dedicated to responding to inquiries regarding this notice]. To learn more about the FTC's case, please call the FTC at 1-877-FTC-HELP.

Sincerely,

[Signature]

[Name – printed]

[Title – President]

Henry Schein Practice Solutions, Inc.

Attachment B

Henry Schein Practice Solutions, Inc. [Return Address]	First-class postage stamp
FORWARDING AND RETURN POSTAGE GUARANTEED	
Dennis Dentist 123 Main Street Anytown, Anystate 00000	
GOVERNMENT ORDERED NOTICE [14 pt. bold type]	

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order from Henry Schein Practice Solutions, Inc. (“Henry Schein”).

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.

Henry Schein develops and sells dental practice management software, including the Dentrax G5 office management software for dental practices. The Commission’s proposed complaint alleges that Henry Schein violated Section 5 of the Federal Trade Commission Act by making false representations to consumers from January 2012 through January 2014 about the security of its Dentrax G5 software. Specifically, the Commission’s proposed complaint alleges that Henry Schein falsely represented that Dentrax G5 provides industry-standard encryption of patient data and helps dentists meet the security requirements of the Health Insurance Portability and Accountability Act (“HIPAA”). The Commission’s proposed complaint alleges that, in truth and in fact, Dentrax G5 used technology that was less secure than industry-standard encryption, and was not capable of helping dentists protect patient data as required by HIPAA.

The proposed order contains provisions designed to prevent Henry Schein from engaging in the same or similar acts or practices in the future.

Part I of the proposed order prohibits Henry Schein from misrepresenting: (A) whether or to what extent any product or service designed to collect or store personal information offers industry-standard encryption; (B) the ability of the product or service to help customers meet regulatory obligations related to

Analysis to Aid Public Comment

privacy or security; or (C) the extent to which a product or service maintains the privacy, security, confidentiality, and integrity of personal information.

Part II of the proposed order requires Henry Schein to notify affected customers that Dentrax G5 uses a less complex encryption algorithm to protect patient data than Advanced Encryption Standard, which is recommended as an industry standard by the National Institute of Standards and Technology. Part II provides for individual notice letters to affected customers and the creation of a toll-free telephone number and email address dedicated to responding to inquiries about the order.

Parts III through V of the proposed order require Henry Schein to pay \$250,000 into a fund to be administered by the Commission. If the Commission decides that direct redress to affected customers is impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines is reasonably related to Henry Schein's practices alleged in the proposed complaint. Any money not used is to be deposited to the U.S. Treasury.

Parts VI, VII, and IX of the proposed order are reporting and compliance provisions. Part VI requires that for five (5) years after the last date of dissemination of any representation covered by the proposed order, Henry Schein will maintain and upon request make available certain materials, including: (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 its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation. Part VII is an order distribution provision that requires Henry Schein to provide the order to current and future principals, officers, directors, and managers, as well as current and future employees having managerial responsibilities with respect to the subject matter of the order. Part IX requires Henry Schein to submit a compliance report within sixty (60) days after service of the order, and additional compliance reports within ten (10) days

Analysis to Aid Public Comment

of written notice from the Commission. Part VIII of the proposed order requires Henry Schein to notify the Commission at least thirty (30) days prior to any corporate changes that may affect compliance obligations. Part X is a provision “sunsetting” the order after 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

Complaint

IN THE MATTER OF

**PROGRESSIVE CHEVROLET COMPANY
AND
PROGRESSIVE MOTORS, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT THE
CONSUMER LEASING ACT AND REGULATION M*Docket No. C-4578; File No. 142 3133
Complaint, June 13, 2016 – Decision, June 13, 2016*

This consent order addresses Progressive Chevrolet Company's and Progressive Motors, Inc.'s lease advertisements. The complaint alleges that respondents violated Section 5(a) of the Federal Trade Commission Act because they failed to disclose, and/or failed to disclose adequately, that their advertised offers required a minimum credit score that is greater than the credit score of the majority of consumers. The complaint also alleges that respondents' leasing advertisements violated the Consumer Leasing Act and Regulation M by failing to disclose or to disclose clearly and conspicuously required terms. The consent order prohibits respondents from advertising the amount of any monthly payment, periodic payment, initial payment, or down payment, or the length of payment term, unless the representation is non-misleading, and respondents clearly and conspicuously disclose all qualifications or restrictions on the consumer's ability to obtain the represented terms, including qualifications or restrictions based on the consumer's credit score.

*Participants*For the *Commission*: Michael B. Rose.For the *Respondents*: David Brown, Stockamp Brown LLC.**COMPLAINT**

The Federal Trade Commission, having reason to believe that Progressive Chevrolet Company, a corporation, also d/b/a Progressive Auto Group, Progressive Jeep, and Progressive Chrysler, and Progressive Motors, Inc., a corporation, also d/b/a Progressive Ram and Progressive Chrysler Jeep Dodge Inc. (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, the Consumer Leasing Act

Complaint

(“CLA”), and its implementing Regulation M, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Progressive Chevrolet Company is an Ohio corporation with its principal office or place of business at 8000 Hills and Dales Road, Massillon, Ohio 44646. Respondent offers automobiles for sale or lease to consumers.

2. Respondent Progressive Motors, Inc. is an Ohio corporation with its principal office or place of business at 7966 Hills and Dales Road, Massillon, Ohio 44646. Respondent offers automobiles for sale or lease to consumers.

3. Respondents have disseminated or caused to be disseminated advertisements to the public that promote consumer leases for automobiles, as the terms “advertisement” and “consumer lease” are defined in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended.

4. 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, 15 U.S.C. § 44.

5. Since at least April 2014, Respondents have disseminated or have caused to be disseminated advertisements to the public promoting the leasing of automobiles online and in print, including but not necessarily limited to the attached Exhibit A. The nearly full-page advertisement contains the following statements and depictions:

Sign & Drive Leases	ALL LEASES ARE
ZERO DOWN!!!!!!	Zip, Zero, Zilch – Nothing Down

6. The advertisement displays two columns – Progressive Chevrolet Company, on the left, advertises three new 2014 Chevrolet vehicles and Progressive Motors, Inc., on the right, advertises six new 2014 Chrysler vehicles. Each pictured vehicle states a lease cost per month. There is no stated length of the lease within close proximity of each vehicle. With each pictured

Complaint

vehicle are the statements repeated from the beginning of the ad: “Sign & Drive” and “Zip, Zero, Zilch – Nothing Down.” These phrases are repeated at least 10 times within the advertisement. Only at the bottom of the advertisement, in fine print and not in close proximity to the advertised vehicles, does the advertisement disclose the term of the lease, that the payment does not include tax, title, and fees, and that the offer is “[s]ubject to 800 beacon [sic] score or higher with approved credit.”

7. The typical consumer does not have an 800 BEACON score or higher. BEACON scores are one type of credit score upon which auto financing entities have relied, and as such are a type of an industry-specific credit score. The typical consumer does not understand what a BEACON score is or know that fewer than 20% of consumers have a BEACON score of 800 or higher. Moreover, the typical consumer does not understand or know what an industry-specific credit score is or how it may differ from a generic credit score.

FEDERAL TRADE COMMISSION ACT VIOLATIONS
Count I

Deceptive Failure to Disclose, and/or Failure to Disclose Adequately, A Material Condition to Obtaining the Lease Monthly Payment

8. In lease advertisements, including but not necessarily limited to Exhibit A, Respondents have represented, expressly or by implication, that consumers can lease the advertised vehicles at the down payment and monthly payment amounts prominently stated in the advertisements.

9. Respondents failed to disclose, and/or failed to disclose adequately, that typical consumers cannot qualify for the advertised terms. This information would be material to consumers in deciding whether to visit Respondents’ dealerships and/or whether to lease an automobile from Respondents. The failure to disclose, and/or failure to disclose adequately, that few consumers will qualify, in light of the representations made, was, and is, a deceptive practice.

Complaint

10. Respondents' practices constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

**VIOLATION OF CONSUMER LEASING ACT AND
REGULATION M**

11. Under Section 184 of the CLA and Section 213.7 of Regulation M, advertisements promoting consumer leases are required to make certain disclosures if they state any of several terms, such as the amount of any payment ("CLA triggering terms"). 15 U.S.C. § 1667c; 12 C.F.R. § 213.7.

12. Respondents' advertisements promoting consumer leases, including but not necessarily limited to those described in Paragraphs 5 and 6, are subject to the requirements of the CLA and Regulation M.

Count II

**Failure to Disclose, and/or Failure to Disclose, Clearly and
Conspicuously, Required Lease Information**

13. Respondents' lease advertisements, including but not necessarily limited to Exhibit A, stated a monthly payment amount, a CLA triggering term, but failed to disclose, and/or failed to disclose clearly and conspicuously, certain additional terms required by the Consumer Leasing Act and Regulation M, including one or more of the following terms:

- a. That the transaction advertised is a lease;
- b. The total amount due prior to or at consummation or by delivery, if delivery occurs after consummation;
- c. The number, amounts, and due dates or periods of scheduled payments under the lease;
- d. A statement of whether or not a security deposit is required; and

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- e. A statement that an extra charge may be imposed at the end of the lease term where the consumer's liability (if any) is based on the difference between the residual value of the leased property and its realized value at the end of the lease term.

14. The lease disclosures required by Regulation M, if provided, are not clear and conspicuous because they appear in fine print and/or in an inconspicuous location.

15. Therefore, the practices set forth in Paragraphs 13 and 14 of this complaint have violated Section 184 of the Consumer Leasing Act, 15 U.S.C. § 1667c, and Section 213.7 of Regulation M, 12 C.F.R. § 213.7.

THEREFORE, the Federal Trade Commission this thirteenth day of June, 2016, has issued this complaint against Respondents.

By the Commission.

Complaint

Exhibit A

Sign & Drive Leases **ALL LEASES ARE**
ZERO DOWN!!!!!! **Zip, Zero, Zilch - Nothing Down!**

<p>2014 CHEVY CRUZE LT</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$169 PER MO. Includes 2 years free maintenance</p>	<p>2014 JEEP COMPASS</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$199 PER MO. Zip Zero Zilch - Nothing Down!</p>
<p>2014 MALIBU LT</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$199 PER MO. Includes 2 years free maintenance</p>	<p>2014 JEEP CHEROKEE</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$299 PER MO. Zip Zero Zilch - Nothing Down!</p>
<p>2014 EQUINOX LT</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$249 PER MO. Includes 2 years free maintenance</p>	<p>2014 DODGE JOURNEY</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$279 PER MO. Zip Zero Zilch - Nothing Down!</p>
<p>ProgressiveChevrolet.com Chevy Runs Deep</p> <p>PROGRESSIVE CHEVROLET 8000 HILLS AND DALES NW - MASSILLON OH 44646 1-800-376-4167</p>	<p>2014 CHRYSLER 300</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$299 PER MO. Zip Zero Zilch - Nothing Down!</p>
	<p>2014 CHRYSLER TOWN & COUNTRY</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$329 PER MO. Zip Zero Zilch - Nothing Down!</p>
	<p>2014 JEEP GR. CHEROKEE</p>  <p>Sign & Drive! Zip Zero Zilch Nothing Down! \$379 PER MO. Zip Zero Zilch - Nothing Down!</p>
	<p>ProgressiveDodge.com CHRYSLER Jeep RAM</p> <p>PROGRESSIVE CHRYSLER • JEEP • DODGE 7966 HILLS AND DALES NW - MASSILLON OH 44646 1-800-580-7886</p>

payments based on 48 month 10,000 mile per year lease plus tax title and fees. 25 cents over mileage penalty. All payments based on 36 month 10,000 mile per year lease plus tax title and fees. 25 cents over mileage penalty. Late price and sale price may be different due to thousands or discounts that do not combine. Subject to 400 credit score or higher with approved credit. Special financing programs available for lower credit scores. Additive equity may affect amount financed. Pictures for illustration purposes. EXPRES: 4/30/2014.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“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 a complaint which the East Central Region-Cleveland proposed to present to the Commission for its consideration and which, if issued, would charge the Respondents with violations of the Federal Trade Commission Act (“FTC Act”), the Consumer Leasing Act (“CLA”), and its implementing Regulation M; and

The Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing a Consent Order (“consent agreement”), which includes: a statement by the Respondents that they neither admit nor deny any of the allegations in the draft complaint except as specifically stated in the consent agreement, and, only for purposes of this action, admit the facts necessary to establish jurisdiction; 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 FTC Act, the CLA, and its implementing Regulation M, 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 for the receipt and consideration of public comments, and having duly considered the comment received from an interested person, now in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Progressive Chevrolet Company is an Ohio corporation with its principal office or place of business at 8000 Hills and Dales Road, Massillon, Ohio 44646. Respondent offers automobiles for sale or lease to consumers.

Decision and Order

2. Respondent Progressive Motors, Inc. is an Ohio corporation with its principal office or place of business at 7966 Hills and Dales Road, Massillon, Ohio 44646. Respondent offers automobiles for sale or lease to consumers.
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:

- A. Unless otherwise specified, “Respondents” shall mean Progressive Chevrolet Company, Progressive Motors, Inc., and their successors and assigns.
- B. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- C. “Clearly and conspicuously” shall mean as follows:
 1. In a print advertisement, the disclosure shall be in a type size, location, and in print that contrasts with the background against which it appears, sufficient for an ordinary consumer to notice, read, and comprehend it.
 2. In an electronic medium, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade and appear on the screen for a duration, and in a location, sufficient for an ordinary consumer to read and comprehend it.

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3. In a television or video advertisement, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade, and appear on the screen for a duration, and in a location, sufficient for an ordinary consumer to read and comprehend it.
 4. In a radio advertisement, the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
 5. In all advertisements, 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 promotion.
- D. “Consumer lease” shall mean a contract in the form of a bailment or lease for the use of personal property by a natural person primarily for personal, family, or household purposes, for a period exceeding four months and for a total contractual obligation not exceeding the applicable threshold amount, whether or not the lessee has the option to purchase or otherwise become the owner of the property at the expiration of the lease, as set forth in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended.
- E. “Lease inception” shall mean prior to or at consummation of the lease or by delivery, if delivery occurs after consummation.
- F. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- G. “Motor vehicle” shall mean:
1. Any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;

Decision and Order

2. Recreational boats and marine equipment;
3. Motorcycles;
4. Motor homes, recreational vehicle trailers, and slide-in campers; and
5. Other vehicles that are titled and sold through dealers.

I.

IT IS HEREBY ORDERED that Respondents and their officers, agents, representatives, and employees shall not, directly or indirectly, expressly or by implication:

- A. In an advertisement concerning the leasing or financing of a motor vehicle, represent the amount of any monthly payment, periodic payment, initial payment, or down payment, or the length of any payment term, unless the representation is non-misleading, and the advertisement clearly and conspicuously discloses all qualifications or restrictions on the consumer's ability to obtain the represented terms, including but not limited to qualifications or restrictions based on the consumer's credit score. *Provided, further,* that, if a majority of consumers likely will not be able to meet a stated credit score qualification or restriction, the advertisement must clearly and conspicuously disclose that fact.
- B. Misrepresent the cost of:
 1. Purchasing a vehicle with financing, including but not limited to, the amount or percentage of the down payment, the number of payments or period of repayment, the amount of any payment, and the repayment obligation over the full term of the loan, including any balloon payment; or

Decision and Order

2. Leasing a vehicle, including but not limited to, the total amount due at lease inception, the down payment, amount down, acquisition fee, capitalized cost reduction, any other amount required to be paid at lease inception, and the amounts of all monthly or other periodic payments.
- C. Misrepresent any other material fact about the price, sale, financing, or leasing of any motor vehicle.

II.

IT IS FURTHER ORDERED that Respondents and their officers, agents, representatives, and employees shall not, in connection with any advertisement for any consumer lease, directly or indirectly, expressly or by implication:

- A. State the amount of any payment or that any or no initial payment is required at lease inception, without disclosing clearly and conspicuously the following terms:
1. that the transaction advertised is a lease;
 2. the total amount due prior to or at consummation or by delivery, if delivery occurs after consummation;
 3. the number, amounts, and timing of scheduled payments;
 4. whether or not a security deposit is required; and
 5. that an extra charge may be imposed at the end of the lease term where the consumer's liability (if any) is based on the difference between the residual value of the leased property and its realized value at the end of the lease term.

Decision and Order

- B. Fail to comply in any respect with Regulation M, 12 C.F.R. Part 213, as amended, and the Consumer Leasing Act, 15 U.S.C. §§ 1667-1667f, as amended.

III.

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 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;
- C. All evidence in their possession or control that contradicts, qualifies, or calls 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; and
- D. Any documents reasonably necessary to demonstrate full compliance with each provision of this order, including, but not limited to, all documents obtained, created, generated, or that in any way relate to the requirements, provisions, or terms of this order, and all reports submitted to the Commission pursuant to this order.

IV.

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, with any electronic signatures complying with the

Decision and Order

requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* 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.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) 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. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The subject line must begin: *In re Progressive Chevrolet Company and Progressive Motors, Inc.*

VI.

IT IS FURTHER ORDERED that Respondents, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

Analysis to Aid Public Comment

VII.

This order will terminate on June 13, 2036, 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 a 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 OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission ("FTC") has accepted, subject to final approval, an agreement containing a consent order from Progressive Chevrolet Company and Progressive Motors, Inc. The proposed consent order has been placed on the public record

Analysis to Aid Public Comment

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 FTC 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.

The respondents are motor vehicle dealers. According to the FTC complaint, respondents advertised that consumers could lease the advertised vehicles at the monthly payment amounts prominently stated in their advertisements. The complaint alleges that respondents violated Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), because they failed to disclose, and/or failed to disclose adequately, that the offer requires a minimum credit score that is greater than the credit score of the majority of consumers. This information would be material to consumers in deciding whether to visit respondents' dealerships and/or whether to lease an automobile from respondents. The complaint also alleges that respondents' leasing advertisements violated the Consumer Leasing Act (CLA) and Regulation M by failing to disclose or to disclose clearly and conspicuously required terms. Specifically, respondents' advertisements prominently stated the monthly payment amounts for a vehicle lease—a triggering term under the CLA—but failed to disclose, or inconspicuously disclosed at the bottom of the ad in much smaller type, the required information set forth by the CLA. The proposed order is designed to prevent the respondents from engaging in similar deceptive practices in the future.

- Part I.A. addresses the Section 5 allegation by prohibiting respondents from advertising the amount of any monthly payment, periodic payment, initial payment, or down payment, or the length of payment term, unless the representation is non-misleading, and respondents clearly and conspicuously disclose all qualifications or restrictions on the consumer's ability to obtain the represented terms, including qualifications or restrictions based on the consumer's credit score. Additionally, if a majority of consumers likely will not be able to meet a credit score qualification or restriction stated in the advertisement,

Analysis to Aid Public Comment

respondents must clearly and conspicuously disclose that fact.

- Part I.B.1. provides that the respondents shall not misrepresent the cost of financing the purchase of an automobile, including by misrepresenting the amount or percentage of the down payment, the number of payments or period of repayment, the amount of any payment, and the repayment obligation over the full term of the loan, including any balloon payment.
- Part I.B.2. provides that the respondents shall not misrepresent the cost of leasing an automobile, including by misrepresenting the total amount due at lease inception, the down payment, amount down, acquisition fee, capitalized cost reduction, any other amount required to be paid at lease inception, and the amounts of all monthly or other periodic payments.
- Part I.C. provides that the respondents shall not misrepresent any other material fact about the price, sale, financing, or leasing of any automobile.
- Part II of the order addresses the CLA and Regulation M allegations by prohibiting lease advertisements that:
 - A. State the amount of any payment or that any or no initial payment is required at lease inception, without disclosing clearly and conspicuously the following terms:
 - that the transaction advertised is a lease;
 - the total amount due prior to or at consummation or by delivery, if delivery occurs after consummation;
 - the number, amounts, and timing of scheduled payments;
 - whether or not a security deposit is required; and

Analysis to Aid Public Comment

- that an extra charge may be imposed at the end of the lease term where the consumer's liability (if any) is based on the difference between the residual value of the leased property and its realized value at the end of the lease term.
- B. Fail to comply in any respect with Regulation M, 12 C.F.R. Part 213, as amended, and the Consumer Leasing Act, 15 U.S.C. §§ 1667-1667f, as amended.
- Part III requires respondents to keep copies of relevant advertisements and materials containing representations.
 - Part IV requires that respondents provide copies of the order to certain of their personnel.
 - Part V requires notification to the Commission regarding changes in corporate structure that might affect compliance obligations under the order. Part VI requires the respondents to file compliance reports with the Commission. Finally, Part VII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

VERY INCOGNITO TECHNOLOGIES, INC.

D/B/A

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

Docket No. C-4580; File No. 162 3034
Complaint, June 21, 2016 – Decision, June 21, 2016

This consent order addresses Very Incognito Technologies, Inc.'s representations to consumers concerning its participation in the Asia-Pacific Economic Cooperation Cross Border Privacy Rules system. The complaint alleges that Vipvape falsely represented that it was a participant in the APEC CBPR system when, in fact, it never sought or obtained certification. The consent order prohibits Vipvape from making misrepresentations about its participation in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including, but not limited to, the APEC CBPR system.

Participants

For the *Commission*: *Monique F. Einhorn*.

For the *Respondent*: *Raphael Pepe, CEO, pro se*.

COMPLAINT

The Federal Trade Commission (“Commission” or “FTC”), having reason to believe that Very Incognito Technologies, Inc., a corporation, has violated the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Very Incognito Technologies, Inc., also doing business as Vipvape, is a California corporation with its principal office or place of business at 2261 Market Street, # 498 San Francisco, CA 94114.
2. Respondent makes and distributes hand-held vaporizers.

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3. The acts and practices of respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.

4. Respondent has set forth on its website, <https://www.vipvape.com/legal/warranty/privacy>, privacy policies and statements about its practices, including statements related to its participation in the Asia-Pacific Economic Cooperation (“APEC”) Cross-Border Privacy Rules (“CBPR”) system.

5. In fact, Respondent has not been certified to participate in the APEC CBPR system.

APEC & the Cross-Border Privacy Rules

6. The APEC CBPR system is a self-regulatory initiative designed to facilitate the protection of consumer data transferred across the APEC region that is enforced by privacy authorities in participating APEC member economies. The CBPR system is based on the APEC Privacy Framework’s nine information privacy principles: preventing harm, notice, collection limitation, use, choice, integrity, security safeguards, access and correction, and accountability. In the United States, the FTC enforces the CBPR system.

7. Companies that seek to participate in the CBPR system must undergo a review by an APEC-recognized accountability agent to establish compliance with the CBPR program requirements. Companies undergo annual reviews to retain their status as certified CBPR participants. The names of certified companies are posted on a website, www.cbprs.org.

Violations of Section 5 of the FTC Act

8. Respondent has disseminated or caused to be disseminated privacy policies and statements on <https://www.vipvape.com/legal/warranty/privacy>, including, but not limited to, the following statements:

Vipvape abides by the Asia-Pacific Economic Cooperation (APEC) Cross Border Privacy Rules

Decision and Order

System. The APEC CPBR system provides a framework for organizations to ensure protection of personal information transferred among participating APEC economies.

9. Through the means described in Paragraph 8, Respondent represented, directly or indirectly, expressly or by implication, that it is certified to participate in the APEC CBPR system.

10. In fact, Respondent is not and never has been certified to participate in the APEC CBPR system. Therefore, the representation set forth in Paragraph 9 is false or misleading.

11. The acts and practices of Respondent as alleged in this complaint constitute 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-first day of June, 2016, has issued this complaint against Respondent.

By the Commission.

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named above in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge Respondent with violation of the Federal Trade Commission Act.

Decision and Order

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. Now, in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent Very Incognito Technologies, Inc., also doing business as Vipvape, is a California corporation with its principal office or place of business at 2261 Market Street, # 498, San Francisco, CA 94114.
2. The Commission has jurisdiction over the subject matter of this proceeding and over Respondent, and the proceeding is in the public interest.

ORDER**Definitions**

For purposes of this Order, the following definitions apply:

- A. “Respondent” means Very Incognito Technologies, Inc., a corporation, also doing business as Vipvape, and its successors and assigns.

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- B. “APEC CBPR” means the Asia-Pacific Economic Cooperation (“APEC”) Cross-Border Privacy Rules (“CBPR”) system.

Provisions**I.****Prohibition against Misrepresentations about Participation in Privacy or Security Programs**

IT IS ORDERED that Respondent and its officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, or sale of any product or service must not misrepresent in any manner, expressly or by implication, the extent to which Respondent is a member of, adheres to, complies with, is certified by, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including APEC CBPR.

II.**Acknowledgments of the Order**

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

- A. Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order.
- B. For twenty (20) years after the issuance date of this Order, Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives with responsibilities related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reporting. Delivery

Decision and Order

must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

- C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

III.**Compliance Report and Notices**

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

- A. Sixty (60) days after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.
- B. Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (1) any designated point of contact; or (2) the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or

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any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

- C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The subject line must begin: *In re Very Incognito Technologies, Inc.*, FTC File No. 1623034.

IV. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for twenty (20) years after the issuance date of the Order, and retain each such record for 5 (five) years. Specifically, Respondent must create and retain the following records:

- A. accounting records showing the revenues from all goods or services sold;
- B. personnel records showing, for each person providing services, whether as an employee or otherwise, that

Decision and Order

person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

- C. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and
- D. a copy of each unique advertisement, promotional material, or other marketing material making any representation subject to this Order, and all materials that were relied upon in making the representation.

V.**Compliance Monitoring**

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

- A. Within ten (10) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.
- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory

Decision and Order

process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VI.
Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate on June 21, 2036, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) 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 Provision 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 Provision. If such complaint is dismissed or a federal court rules that 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 as to Respondent will terminate according to this Provision 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 to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, a consent agreement applicable to Very Incognito Technologies, Inc. dba Vipvape (“Vipvape”).

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 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.

This matter concerns alleged false representations that Vipvape made to consumers concerning its participation in the Asia-Pacific Economic Cooperation (“APEC”) Cross Border Privacy Rules (“CBPR”) system. The APEC CBPR system is a voluntary, enforceable mechanism that certifies a company’s compliance with the principles in the CBPR and facilitates privacy-respecting transfers of data amongst APEC member economies. The APEC CBPR system is based on nine data privacy principles: preventing harm, notice, collection limitation, use choice, integrity, security safeguards, access and correction, and accountability. Companies that seek to participate in the APEC CBPR system must undergo a review by an APEC-recognized Accountability Agent, which certifies companies that meet the standards.

Companies under the FTC’s jurisdiction are eligible to apply for APEC CBPR certification. The names of certified companies are posted on a public-facing website, www.cbprs.org. Companies must re-apply annually in order to retain their status as current participants in the APEC CBPR system. A company that falsely claims APEC CBPR participation may be subject to an enforcement action based on the FTC’s deception authority under Section 5 of the FTC Act.

Analysis to Aid Public Comment

Vipvape makes and distributes hand-held vaporizers. According to the Commission's complaint, Vipvape has set forth on its website, <https://www.vipvape.com/content/legal/warranty/privacy>, privacy policies and statements about its practices, including statements related to its participation in the APEC CBPR system.

The Commission's complaint alleges that Vipvape falsely represented that it was a participant in the APEC CBPR system when, in fact, it never sought or obtained certification.

Part I of the proposed order prohibits Vipvape from making misrepresentations about its participation in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including, but not limited to, the APEC CBPR system.

Parts II through VI of the proposed order are reporting and compliance provisions. Part II requires acknowledgment of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that Vipvape submit an initial compliance report to the FTC. Part IV requires Vipvape to retain documents relating to its compliance with the order for a five-year period. Part V mandates that Vipvape make available to the FTC information or subsequent compliance reports, as requested. Part VI 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 complaint or order or to modify the order's terms in any way.

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS

IN THE MATTER OF

MYLAN N.V.

Docket No. C-4557. Order, February 19, 2016

Letter terminating the Monitor's appointment.

LETTER ORDER TERMINATING MONITOR

F. William Rahe
Quantic Regulatory Services, LLC

Re: In the Matter of Mylan N.V., File No. 151-0129, Docket No. C-4557¹

Dear Mr. Rahe:

On November 2, 2015, the Commission appointed you to serve as the Interim Monitor under the Order to Maintain Assets and the proposed Decision and Order in the above-described matter. Because Respondent Mylan N.V. failed to consummate its proposed acquisition of Perrigo Company plc, the divestiture requirements of Paragraph II of the proposed Decision and Order and related provisions will not become operative. Furthermore, the Order to Maintain Assets terminated by its own terms on November 13, 2015, *i.e.*, the Expiration Date. Accordingly, your continued service as an Interim Monitor will no longer be necessary in this matter. Therefore, the Commission has decided to terminate your service as Interim Monitor in this matter effective immediately.

By direction of the Commission.

¹ As used in this letter, capitalized terms are as defined in the proposed Decision and Order in this matter.

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IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, March 18, 2016

Order denying respondent's motion to stay the evidentiary hearing, without staying discovery or any other scheduling order deadlines, "until 60 days after entry of a ruling" on the Commission's district court complaint for a preliminary injunction.

**ORDER DENYING MOTION TO STAY THE ADMINISTRATIVE
HEARINGS**

On December 17, 2015, the Commission issued an administrative complaint alleging that an affiliation agreement by the three Respondents in this administrative proceeding violates Section 5 of the Federal Trade Commission Act, and, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. On December 21, 2015, pursuant to Section 13(b) of the FTC Act and Section 16 of the Clayton Act, the Commission filed a complaint in United States District Court for the Northern District of Illinois seeking a temporary restraining order and a preliminary injunction to prevent Respondents from consummating their proposed merger until final resolution of this administrative proceeding. Compl., FTC v. Advocate Health Care Network, No. 1:15-cv-11473 (N.D. Ill.)(Dec. 21, 2015). In accordance with Commission Rule 3.11(b) (4), the administrative complaint provides that the evidentiary hearing shall begin on May 24, 2016.

On February 5, 2016, Respondents filed a motion to stay the evidentiary hearing, without staying discovery or any other scheduling order deadlines, "until 60 days after entry of a ruling" on the Commission's district court complaint for a preliminary

Interlocutory Orders, Etc,

injunction. Motion at 1, 5.¹ Complaint Counsel opposes the motion.

Commission Rule 3.41(f) provides, in relevant part, that a pending “collateral federal court action that relates to the administrative adjudication shall not stay the proceeding unless a court of competent jurisdiction, or the Commission for good cause, so directs.” 16 C.F.R. § 3.41(f) (2016). Respondents rest their motion to stay on the suggestion that the district court may not rule on the preliminary injunction request until after the administrative hearing begins on May 24. Respondents’ conjecture, however, is not a basis for delaying the administrative hearing. The preliminary injunction hearing is scheduled to begin on April 6, 2016, and is expected to last no more than six days. At this time, we see no conflict between the two proceedings or any other reason that would justify staying the administrative hearing. Furthermore, as reflected in the Commission’s rules, the Commission has made a commitment to move forward as expeditiously as possible with administrative hearings on the merits. We therefore find that no good cause exists to grant Respondents’ motion to stay.

Accordingly, **IT IS HEREBY ORDERED** that Respondents’ February 5, 2016 Motion To Stay the Administrative Hearing is hereby **denied** without prejudice.

By the Commission.

¹ On February 24, 2016, Respondents sought leave to file a Reply, which the Commission grants.

Interlocutory Orders, Etc.

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER,
AND
PINNACLEHEALTH SYSTEM**

Docket No. 9368. Order, March 21, 2016

Order denying respondent's motion to stay the evidentiary hearing, without staying discovery or any other scheduling order deadlines, "until 60 days after entry of a ruling" on the Commission's district court complaint for a preliminary injunction.

ORDER DENYING MOTION TO STAY THE ADMINISTRATIVE
HEARINGS

On December 8, 2015, the Commission issued an administrative complaint alleging that a merger agreement between the Respondents in this administrative proceeding violates Section 5 of the Federal Trade Commission Act, and, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. On December 9, 2015, pursuant to Section 13(b) of the FTC Act and Section 16 of the Clayton Act, the Commission filed a complaint in United States District Court for the Middle District of Pennsylvania seeking a temporary restraining order and a preliminary injunction to prevent Respondents from consummating their proposed merger until final resolution of this administrative proceeding. Compl., *FTC v. Penn State Hershey Med. Ctr.*, No. 1:15-cv-2362-JEJ (M.D. Pa.) (Dec. 9, 2015). In accordance with Commission Rule 3.11(b) (4), the administrative complaint provides that the evidentiary hearing shall begin on May 17, 2016.

On February 22, 2016, Respondents filed a motion to stay the evidentiary hearing, without staying discovery or any other scheduling order deadlines, "until 60 days after the ruling" on the Commission's district court complaint for a preliminary injunction. Motion at 1. Complaint Counsel opposes the motion.

Commission Rule 3.41(f) provides, in relevant part, that a pending "collateral federal court action that relates to the

Interlocutory Orders, Etc,

administrative adjudication shall not stay the proceeding unless a court of competent jurisdiction, or the Commission for good cause, so directs.” 16 C.F.R. § 3.41(f) (2016). Respondents rest their motion to stay on the suggestion that the district court may not rule on the preliminary injunction request until after the administrative hearing begins on May 17, 2016. Respondents’ conjecture, however, is not a basis for delaying the administrative hearing. The preliminary injunction hearing is scheduled to begin on April 11, 2016; will be “held over no more than five (5) days;” and will conclude no later than April 15, 2016. Stip. Case Mgmt. Order at 10, *FTC v. Penn State Hershey Med. Ctr.*, No. 1:15-cv-2362-JEJ (M.D. Pa.) (Jan. 19, 2016). At this time, we see no conflict between the two proceedings or any other reason that would justify staying the administrative hearing. Furthermore, as reflected in the Commission’s rules, the Commission has made a commitment to move forward as expeditiously as possible with administrative hearings on the merits. We therefore find that no good cause exists to grant Respondents’ motion to stay.

Accordingly, **IT IS HEREBY ORDERED** that Respondents’ February 22, 2016 Motion To Stay the Administrative Hearing is hereby **denied** without prejudice.

By the Commission.

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IN THE MATTER OF

**CABELL HUNTINGTON HOSPITAL, INC.,
PALLOTTINE HEALTH SERVICES, INC., AND
ST. MARY'S MEDICAL CENTER, INC.**

Docket No. 9366. Order, March 24, 2016

Order granting Complaint Counsel and Respondents Joint Expedited Motion to withdraw this matter from adjudication for thirty days.

**ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THIRTY
DAYS**

On November 5, 2015, the Commission issued an administrative complaint alleging that an agreement among Respondents Cabell Huntington Hospital, Inc.; Pallottine Health Services, Inc.; and St. Mary's Medical Center, Inc. ("Respondents") – pursuant to which Cabell Huntington Hospital would acquire all the assets of St. Mary's Medical Center – violates Section 5 of the FTC Act, 15 U.S.C. § 45, and that if the acquisition were consummated, it would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act. In accordance with Commission Rule 3.11(b)(4), the administrative complaint provides that the evidentiary hearing shall begin on April 5, 2016.

On March 16, 2016, Complaint Counsel and Respondents filed a Joint Expedited Motion ("Joint Motion") to withdraw this matter from adjudication for thirty days, or in the alternative, to delay the commencement of the administrative evidentiary hearing until at least April 26, 2016. The Parties represent that legislation recently passed by the West Virginia legislature and now signed by the Governor of West Virginia "raises significant new issues about whether the Transaction may become immune from federal antitrust law" and "potentially creates a defense for Respondents that did not exist at the time the Commission voted to initiate the Part 3 action." Joint Motion at 5.

In light of those developments, Complaint Counsel and Respondents believe that there is good cause for the Commission

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to remove this matter from adjudication for thirty days. They argue that withdrawing the matter from adjudication will enable the Commission to review the legislation – and to hear from both Complaint Counsel and Respondents as to the relevance of the legislation to this proceeding – prior to “the expenditure of significant Commission, party, and third-party resources attendant to pre-trial preparations and the start of a full trial on the merits.” Joint Motion at 5.

The Commission is committed to moving forward as expeditiously as possible with adjudicative proceedings.¹ We have determined, however, that withdrawing this matter from adjudication for a short period of time – in conjunction with the Respondents’ agreement not to consummate the proposed acquisition during that period (*see* Joint Motion at 2) – will give us an opportunity to evaluate the impact, if any, of the state legislation without any adverse effects on competition or consumer interests. We therefore find there is good cause to withdraw this matter from adjudication for thirty days. Accordingly,

IT IS HEREBY ORDERED that this matter in its entirety be, and it hereby is, withdrawn from adjudication, and that all proceedings before the Administrative Law Judge are hereby stayed, until 11:59 p.m. EDT on April 25, 2016.

By the Commission.

¹ *See In re Advocate Health Care Network*, Docket No. 9369, Order Denying Motion To Stay the Evidentiary Hearing (March 18, 2016); Rule 3.1, 16 C.F.R. § 3.1 (“[T]he Commission’s policy is to conduct [adjudicative] proceedings expeditiously.”); Rule 3.41(b), 16 C.F.R. § 3.41(b) (“Hearings shall proceed with all reasonable expedition . . .”).

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IN THE MATTER OF

**MCWANE, INC.,
AND
STAR PIPE PRODUCTS, LTD.**

Docket No. 9351. Order, April 1, 2016

Order enhancing the Star Pipe Order's reporting and notification provisions.

ORDER TO SHOW CAUSE AND ORDER MODIFYING ORDER

On May 8, 2012, the Federal Trade Commission ("Commission") issued a Decision and Order ("Star Pipe Order") in Docket No. 9351, resolving claims as to Respondent Star Pipe Products, Ltd. ("Star Pipe") contained in the Complaint that the Commission had issued against Star Pipe and McWane, Inc. ("McWane"), on January 4, 2012. The Complaint alleged that McWane and Star Pipe, along with their competitor Sigma Corporation ("Sigma"), conspired to raise and stabilize the prices at which Ductile Iron Pipe Fittings ("DIPF") are sold in the United States.¹ The Complaint alleged that McWane, Sigma, and Star Pipe (collectively, the "Sellers") exchanged sales data in order to facilitate this price coordination, in violation of Section 5 of the Federal Trade Commission Act, as amended 15 U.S.C. §45. Star Pipe denied these allegations but agreed to settle the matter through entry of the Order shortly after the Complaint was issued, but before any testimony was taken.

Since entry of the Star Pipe Order, the Commission has investigated whether Star Pipe engaged in conduct that violated that order. Star Pipe, while not admitting any violation, has agreed to certain modifications and enhancements of the Star Pipe Order, to resolve the matter. It has waived any further procedures and has

¹ McWane declined to settle this matter, and the Commission pursued the litigation as to it. See In the Matter of McWane, Inc., and Star Pipe Products, Ltd., Docket 9351, *aff'd*, McWane, Inc. v. FTC, 783 F.3d 814 (11th Cir. 2015), *cert. denied* (U.S. Mar. 21, 2016) (No. 15-706). Sigma had agreed to entry of an order prior to issuance of the Commission's Complaint against Star and McWane. See In the Matter of Sigma Corporation, Docket C-4347.

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agreed to issuance of this Order to Show Cause and Order Modifying Order.

Paragraph II.C. of the Star Pipe Order requires Star Pipe, among other things, to cease and desist from entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors to Communicate or exchange Competitively Sensitive Information.² The Order defines “Competitor” to mean Star Pipe “and any Person that . . . (1) manufactures DIPF; (2) causes DIPF to be manufactured; or (3) imports DIPF.” Paragraph II.E. requires Star to cease and desist from attempting to engage in any of the prohibited activities in Paragraph II.C.³

In August 2012, Star Pipe began to receive Competitively Sensitive Information regarding DIPF from an independent Sigma sales agent. The information Star Pipe received was precisely the type of information Star Pipe was prohibited from communicating to or agreeing to receive from a Competitor. In violation of the Star Pipe Order’s proscriptions, however, Star Pipe continued to receive and encourage the delivery of this information until early July 2013.

Sigma apparently was unaware of its agent’s behavior, but at least one of Star Pipe’s senior executives knew that Star Pipe was receiving Competitively Sensitive Information. On May 13, 2013, Star Pipe filed its first annual report of compliance, required by Paragraph V. Although Star Pipe had been receiving Sigma’s Competitively Sensitive Information since at least August 17, 2012, it failed to disclose this activity in its report. The

2 Competitively Sensitive Information is defined at Order Paragraph I.D. to mean, with certain exceptions, any information regarding the cost, price, output, or customers of or for DIPF marketed by Respondent or any other Competitor, regardless of whether the information is prospective, current or historical, or aggregated or disaggregated. Among exclusions from this definition is information received from a customer regarding a price quoted to that customer by a Competitor.

3 Sigma is under an identically written prohibition in Paragraph II of its order.

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Commission learned of this activity when alerted by counsel for Sigma.

Star Pipe has denied that it violated the Star Pipe Order. It has asserted that it never solicited the information received from the Sigma independent sales agent; that the independent sales agent is not a Competitor; that the independent sales agent's job did not include selling DIPF; that the independent sales agent ignored Star Pipe's request to stop sending the information; and that early in July 2013, Star Pipe, through its counsel, notified Sigma's counsel of Star Pipe's receipt of Sigma information. The Commission considered these assertions, but finds reason to believe that Star Pipe violated the Star Pipe Order's prohibitions against attempting to agree to receive a competitor's Competitively Sensitive Information.

Although DIPF was not a product sold by the independent Sigma agent, as a member of the Sigma sales force he received the same daily and weekly confidential sales and pricing information that the employed sales force for DIPF received. Each email forwarded by the independent sales agent to Star Pipe was an email he received as one of the addressees identified as "SST-All@Sigmaco.com." Moreover, Star Pipe was aware that the information it was receiving contained Sigma's confidential sales data. There is evidence that the information may have been useful to Star Pipe and that Star Pipe encouraged its continued receipt. Finally, Star Pipe has produced no documentary evidence in support of its assertion that it asked the agent to stop communicating the Competitively Sensitive Information.

In view of the foregoing, the Commission has determined, in its discretion, that it is in the public interest to reopen the proceeding in Docket No. 9351, pursuant to Section 3.72(b) of the Commission's Rules of Practice, 16 CFR § 3.72(b), and to modify the Star Pipe Order by adding provisions intended to enhance the Star Pipe Order's reporting and notification provisions. These provisions are set forth in new subparagraphs IV.D. through IV.G. Paragraph IV.D. specifies additional personnel Star Pipe is obligated to notify of the Star Pipe Order's requirements; Paragraph IV.E. requires Star Pipe to train certain identified personnel regarding compliance with the Order; Paragraph IV.F.

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requires Star Pipe to notify the Commission of the transmission or receipt of any Competitively Sensitive Information to or from Competitors; and Paragraph IV.G. requires Star Pipe to submit annually an affidavit stating that no such Competitively Sensitive Information has been sent or received.

Star Pipe denies that it has violated the terms of the Order, and Star Pipe does not agree with the facts and conclusions as stated herein. In settlement of the Commission's claims regarding violation of the terms of the Order as described, however, Star Pipe has consented to the changes contained in this Modifying Order, and waives any further rights it may have under Section 3.72(b) of the Commission's Rules of Practice, 16 C.F.R. §3.72(b). Accordingly,

IT IS ORDERED that this matter be, and it hereby is, reopened; and

IT IS FURTHER ORDERED that Paragraph IV of the Star Pipe Order in Docket No. 9351 be, and hereby is, modified to add the following sub-paragraphs, which shall read as follows:

ORDER MODIFYING ORDER

IV.

- D. Distribute by first-class mail, return receipt requested, or by electronic mail with return confirmation, a copy of this Order Modifying Order:
1. Within thirty (30) days from the date this Order Modifying Order is issued, to each of its officers, directors, and Designated Managers (including General Sales Managers, Division Managers, any other Person with pricing authority, and National Market Managers); and
 2. For five (5) years from the date this Order Modifying Order is issued, within sixty (60) days to each Person who becomes an officer, director, or Designated Manager (including General Sales Manager, Division Manager, any other Person with

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pricing authority, and National Market Manager) and who did not previously receive a copy of this Order Modifying Order.

- E. For five (5) years from the date this Order Modifying Order is issued, conduct an annual program to train each officer, director, and Designated Manager (including General Sales Manager, Division Manager, any other Person with pricing authority, and National Market Manager) as to the prohibitions and requirements of the Star Pipe Order and the Order Modifying Order.
- F. For ten (10) years from the date this Order Modifying Order is issued, notify the Commission within thirty (30) days after any of the individuals specified at Paragraph IV. becomes aware of either:
1. the transmission by any officer, director, employee, or agent of Respondent of Respondent's Competitively Sensitive Information to a Competitor (including the Competitor's independent sales agent), or
 2. the receipt by any officer, director, employee, or agent of Respondent of a Competitor's Competitively Sensitive Information from a Competitor (including the Competitor's independent sales agent);

whether such transmission or receipt is by United States mail, facsimile, email to or from a Respondent email account or to or from a private email account.

- G. For five (5) years from the date this Order Modifying Order is issued, submit annually, on the date when reports required by Paragraph V of the Star Pipe Order are due (until 2021), an affidavit signed by the individual at Respondent responsible for its compliance with the Star Pipe Order and this

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Order Modifying Order that no Competitively Sensitive Information has been sent or received by Respondent to or from a Competitor (including the Competitor's independent sales agent).

By the Commission.

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Attachment

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)	
McWane, Inc.,)	
a corporation, and)	
Star Pipe Products, Ltd.)	Docket No. 9351
a limited partnership.)	

AGREEMENT CONTAINING ORDER TO SHOW CAUSE AND
ORDER MODIFYING ORDER ISSUED AGAINST STAR PIPE PRODUCTS, LTD.

The Federal Trade Commission ("Commission"), having initiated an investigation of certain conduct of Star Pipe Products, Ltd. ("Star Pipe") related to Star Pipe's compliance with its obligations under the Decision and Order that the Commission issued against Star Pipe in *In the Matter of McWane, Inc., and Star Pipe Products, Ltd.*, Docket No. 9351, on May 8, 2012 ("Star Pipe Order"), and it now appearing that Star Pipe, hereinafter sometimes referred to as "Respondent," is willing to enter into this Agreement Containing Order to Show Cause and Order Modifying Order ("Consent Agreement") agreeing to modifications of the Star Pipe Order as described in the attached Order Modifying Order ("Modifying Order");

IT IS HEREBY AGREED by and between Respondent, its duly authorized officer and attorney, and counsel for the Commission that:

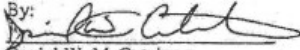
- i. Respondent Star Pipe is a limited partnership organized, existing, and doing business under and by virtue of the laws of the state of Texas, with its office and principal place of business located at 4018 Westhollow Parkway, Houston, Texas 77082.
2. Respondent waives:
 - a. Any further procedural steps;
 - b. Any requirement that the Commission's Modifying Order, attached hereto and made a part hereof, contain a statement of findings of fact and conclusions of law;
 - c. Its rights under the show cause procedures set forth in Section 3.72(b) of the Commission's Rules of Practice, 16 C.F.R. § 3.72(b);
 - d. All rights to seek judicial review or otherwise to challenge or contest the validity of the Modifying Order entered pursuant to this Consent Agreement; and
 - e. Any claim under the Equal Access to Justice Act.

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3. This Consent Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Consent Agreement is accepted by the Commission, it may be placed on the public record for a period of thirty (30) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Consent Agreement and so notify Respondent, in which event it will take such action as it may consider appropriate, or issue and serve the Modifying Order, in disposition of the proceeding.
4. This Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that any law or order has been violated.
5. When final, the Modifying Order shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The Modifying Order shall become final upon service. Delivery of the Modifying Order to Respondent by any means provided in Commission Rule 4.4(a), 16 C.F.R. § 4.4(a) – including, but not limited to, delivery to Respondent's Counsel as identified in the Consent Agreement – shall constitute service. Respondent waives any right it may have to any other manner of service.
6. The Order to Show Cause may be used in construing the terms of the Modifying Order, and no agreement, understanding, representation, or interpretation not contained in the Order to Show Cause or the Modifying Order may be used to vary or contradict the terms of the Modifying Order.
7. By signing the Consent Agreement, Respondent represents and warrants that it can accomplish the full relief contemplated by the attached Modifying Order and that all parents, subsidiaries, affiliates, and successors necessary to effectuate the full relief contemplated by the Consent Agreement are parties to the Consent Agreement and are bound thereby as if they had signed this Consent Agreement and were made parties to this proceeding and to the Modifying Order.
8. Respondent has read the draft of the Order to Show Cause and the Modifying Order. Respondent understands that once the Modifying Order has been issued, Respondent will be required to file one or more compliance reports showing how it has complied, and is complying with the Modifying Order. Respondent agrees to comply with the terms of the proposed Modifying Order from the date it signs this Consent Agreement; provided, however, that Respondent will have no obligation to comply with the terms of the proposed Modifying Order if the Commission withdraws its acceptance of this Consent Agreement. Respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the Modifying Order after it becomes final.

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STAR PIPE PRODUCTS, LTD.

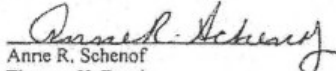
By: 
Daniel W. McCutcheon
President
Star Pipe Products, Ltd.

Dated: _____, 2016



Gregory S.C. Huffman, Esq.
Thompson & Knight LLP
Counsel for Star Pipe Products, Ltd.

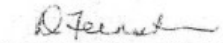
Dated: _____, 2016

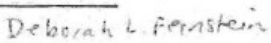
FEDERAL TRADE COMMISSION


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Deborah L. Feinstein

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IN THE MATTER OF

**PFIZER INC.,
AND
WYETH**

Docket No. C-4267. Order, April 4, 2016

Order granting the Petition of Respondent Pfizer Inc. to Reopen and Modify Decision and Order for the limited purpose of setting aside the Order as to Pfizer, and continuing as to its successor, Zoetis.

ORDER REOPENING AND MODIFYING ORDER

Pfizer Inc. (“Pfizer”) filed a Petition of Respondent Pfizer Inc. to Reopen and Modify Decision and Order (“Petition”) on December 8, 2015. Pfizer is a Respondent to the consent order issued by the Commission in *Pfizer Inc. et al.*, Docket No. C-4267 (“Order”), which required Pfizer to divest certain animal health assets and imposed related remedial obligations. Since the divestiture, Pfizer has transferred its animal health business, and all related assets and liabilities, to Zoetis Inc. (“Zoetis”), and Zoetis has expressly agreed to be bound to the Order. Pfizer now asks that this proceeding be reopened for the limited purpose of setting aside the Order as to Pfizer, and continuing as to its successor, Zoetis. Pfizer’s Petition was available for public comment for thirty days until January 22, 2016 and no public comments were filed. For the reasons stated below, the Commission has determined to grant Pfizer’s Petition and reopen and modify the Order as requested.

BACKGROUND

The Commission issued the Order on January 25, 2010, to resolve concerns regarding the competitive impact of Pfizer’s 2009 acquisition of Wyeth. At the time, Pfizer and Wyeth were both involved in human health and animal health businesses. The proposed combination of Pfizer and Wyeth created competitive concerns in a number of animal health markets, but it did not raise concerns regarding human health markets. To resolve these concerns, the Order required Pfizer to divest a substantial number of animal health products and related assets to Boehringer

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Ingelheim Vetmedica Inc. (“BIVI”), and certain equine anthelmintic product assets to Virbac Corporation. The Order also imposes a number of continuing obligations to support the divestitures and the remedial purposes of the Order. These obligations include maintaining the confidentiality of information regarding the divested assets, providing assistance to respond to litigation regarding Product Intellectual Property (as defined in the Order), and filing annual compliance reports. Pfizer has completed the required divestitures but remains subject to the continuing obligations until the Order terminates on January 25, 2020.

PFIZER’S PETITION

Pfizer requests that the Order be set aside as to Pfizer because it no longer owns or controls the animal health assets and business that are relevant to the Order’s continuing obligations. On January 28, 2013, Pfizer and Zoetis entered into a Contribution Agreement, and on February 6, 2013, the parties entered into a Global Separation Agreement. Through these agreements, Pfizer transferred all of its animal health assets and liabilities to Zoetis.¹ Pfizer continued to retain an interest in Zoetis until June 24, 2013, when Pfizer completed a stock exchange offer and divested itself of all interest in Zoetis.² Through these transactions, Pfizer exited the animal health business and Zoetis became a successor to Pfizer under the Order.

Zoetis recognizes its obligations under the Order and has acted as a successor since acquiring Pfizer’s animal health business.³ Since Zoetis acquired Pfizer’s animal health assets, it has assumed responsibility for complying with the Order and has filed all required compliance reports jointly with Pfizer. Further, Zoetis, Pfizer and BIVI have agreed that if the Commission grants Pfizer’s petition, Pfizer will assign to Zoetis the divestiture

1 Petition at page 4.

2 *Id.*

3 Petition at page 5.

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agreements Pfizer and BIVI entered pursuant to this Order.⁴ Finally, Pfizer represents that it has no plans or present intention to reacquire the assets transferred to Zoetis or to reenter the animal health business.⁵

STANDARD FOR REOPENING AND MODIFYING A FINAL ORDER

Pfizer's Petition was filed pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b). Section 5(b) provides that the Commission shall reopen an order to consider whether it should be modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require.⁶ A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that these changes eliminate the need for the order or make continued application of it inequitable or harmful to competition.⁷ Section 5(b) also provides that the Commission may reopen and modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest so requires. Respondents are therefore invited in petitions to reopen to show how the public interest warrants the requested modification.⁸

4 *Id.* Pfizer has also requested Commission approval to assign the Order's Remedial Agreements regarding BIVI to Zoetis. Petition at page 1.

5 Petition at page 5.

6 *See also Supplementary Information*, Amendment to the Commission's Rules of Practice § 2.51(b), 16 C.F.R. 2.51(b) (August 15, 2001).

7 S. Rep. No. 96-500, 96th Cong., 2d Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana-Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished) ("Hart Letter"). *See also United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) ("A decision to reopen does not necessarily entail a decision to modify the Order. Reopening may occur even where the petition itself does not plead facts requiring modification.").

8 Hart Letter at 5; 16 C.F.R. § 2.51.

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In all instances, whether the request is based on changed conditions or on public interest grounds, respondents' showing must be supported by evidence that is credible and reliable. Commission Rule 2.51(b) requires a "satisfactory showing" to include affidavits setting forth admissible facts, and that all information and material that the requester wishes the Commission to consider be contained in the request at the time of filing.⁹

If, after determining that the requester has made the required showing, the Commission decides to reopen the order, the Commission will then consider and balance all of the reasons for and against modification. In no instance does a decision to reopen an order oblige the Commission to modify it,¹⁰ and the burden remains on the requester in all cases to demonstrate why the order should be reopened and modified. The petitioner's burden is not a light one in view of the public interest in repose and the finality of the Commission's orders.¹¹

THE ORDER WILL BE REOPENED AND MODIFIED

Pfizer has made the requisite showing that changed conditions and the public interest support setting aside the Order as to Pfizer. Pfizer's exit from the animal health business and its spin-off of its animal health assets and liabilities to Zoetis is a material change of fact. Zoetis is a successor to Pfizer under the Order and is in the best position to fulfill the continuing obligations of the Order. Further, Zoetis has acknowledged and complied with the continuing obligations under the Order since acquiring Pfizer's animal health assets. Pfizer has no interest in Zoetis or in any animal health business and, as such, does not have the interest or ability to interfere with the remedial purposes of the Order. Neither the interests of the Commission nor the public interest require Pfizer to remain subject to the Order. Further, setting

9 16 C.F.R. § 2.51 (b).

10 See *United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) (reopening and modification are independent determinations).

11 See *Federated Department Stores, Inc. v. Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

Interlocutory Orders, Etc,

aside the Order as to Pfizer is consistent with past Commission rulings on similar petitions.¹²

Accordingly,

IT IS ORDERED that the Order in Docket No. C-4267 be, and it hereby is, reopened; and

IT IS FURTHER ORDERED that the Order be, and it hereby is, set aside as to Pfizer Inc. but not as to Pfizer Inc.'s successor, Zoetis Inc., and, consistent therewith, the assignment to Zoetis Inc. of the Order's Remedial Agreements regarding BIVI is hereby approved.

By the Commission.

¹² See, e.g., *Duke Energy Corp., et al.*, Docket No. C-3932, Order Reopening and Modifying Order (Sept. 26, 2007) (order set aside as to Duke Energy after sale of assets in the relevant business to Spectra Energy); see also *AEA Investors 2006 Fund L.P., et al.*, Docket No. C-4297, Order Reopening and Modifying Final Order (Apr. 30, 2013); *Koninklijke Ahold, N.V.*, Docket No. C-4027, Order Reopening and Modifying Order (July 10, 2007) and Order Reopening and Modifying Order (July 21, 2006); *Entergy Corporation, et al.*, Docket No. C-3998, Order Reopening and Setting Aside Order (July 1, 2005).

Interlocutory Orders, Etc.

IN THE MATTER OF

**CABELL HUNTINGTON HOSPITAL, INC.,
PALLOTTINE HEALTH SERVICES, INC.,
AND
ST. MARY'S MEDICAL CENTER, INC.**

Docket No. 9366. Order, April 22, 2016

Order extending the withdrawal of this matter from adjudication until a short time after the WVHCA determines whether to approve or deny Cabell's application for approval.

ORDER EXTENDING WITHDRAWAL FROM ADJUDICATION

On November 5, 2015, the Commission issued an administrative complaint challenging Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center. On March 24, 2016, the Commission issued an Order withdrawing this matter from adjudication, and staying all proceedings before the Administrative Law Judge, until April 25, 2016. We found good cause to take these steps in order to evaluate the impact, if any, of a newly enacted West Virginia statute, which empowers the West Virginia Health Care Authority ("WVHCA") to prospectively review and approve or disapprove certain "cooperative agreements" between hospitals.¹

On March 22, 2016, the WVHCA informed Cabell that it would have to secure WVHCA approval before consummating the proposed acquisition, and Cabell filed the requisite application on March 25, 2016. On April 18, 2016, Complaint Counsel and Respondents filed a Joint Motion to extend the withdrawal of this matter from adjudication and continue the current stay of proceedings until 14 days after the WVHCA "issues its written decision" regarding Cabell's application.² As a condition of their

¹ See W. Va. Code § 16-29B-28 (a)(2).

² Joint Motion at 1.

Interlocutory Orders, Etc,

Joint Motion, “Respondents agree not to consummate the Transaction while this matter is withdrawn from adjudication.”³

As we stated in our March 24 Order, we are committed to moving forward as expeditiously as possible with adjudicative proceedings.⁴ We have determined, however, that there is good cause to extend the withdrawal of this matter from adjudication until a short time after the WVHCA determines whether to approve or deny Cabell’s application. The new statute requires WVHCA to issue a written decision no more than 75 days after receipt of Cabell’s completed application,⁵ and as noted above, Respondents have agreed not to consummate the proposed acquisition while this matter is withdrawn from adjudication.⁶ As a result, extending the withdrawal from adjudication until 14 days after the WVHCA issues its decision will enable us to evaluate its significance without any adverse effects on competition or consumer interests. We have therefore determined to grant the Joint Motion. Accordingly,

IT IS HEREBY ORDERED that the withdrawal of this matter in its entirety from adjudication, and the stay of all proceedings before the Administrative Law Judge, are extended until 11:59 p.m. EDT on the 14th calendar day after the West Virginia Health Care Authority issues its written decision, pursuant to Section 16-29B-28(e)(3) of the Code of West Virginia, regarding the Application for Approval of Cooperative

³ *Id.* at 3 & n.3.

⁴ See Commission Rule 3.1, 16 C.F.R. § 3.1 (“[T]he Commission’s policy is to conduct [adjudicative] proceedings expeditiously.”); Rule 3.41(b), 16 C.F.R. § 3.41(b) (“Hearings shall proceed with all reasonable expedition . . .”).

⁵ Joint Motion at 2, *citing* W. Va. Code § 16-29B-28(e)(3). If the WVHCA requests additional information, it may take an additional 15 days following receipt of that information to approve or deny Cabell’s application. Joint Motion at 2 note 2, *citing* W. Va. Code § 16-29B-28(e)(3).

⁶ If the WVHCA has not issued a written decision within 120 days of this Order, (1) the Respondents may provide Complaint Counsel and the Commission with seven-days’ notice of their intent to consummate the transaction and (2) the Commission may return this matter to adjudication upon providing the Respondents with seven days’ notice.

Interlocutory Orders, Etc.

Agreement (Acquisition of St. Mary's Medical Center) filed by
Respondent Cabell on March 25, 2016.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

STAPLES, INC.
AND
OFFICE DEPOT, INC.

Docket No. 9367. Order, April 29, 2016

Order granting Complaint Counsel and Respondents Joint Expedited Motion seeking a 21-day continuance of the evidentiary hearing and related pre-hearing deadlines.

ORDER CONTINUING ADMINISTRATIVE PROCEEDING FOR 21 DAYS

On December 7, 2015, the Commission issued an administrative complaint alleging that a merger agreement between Respondents Staples, Inc. and Office Depot, Inc. violates Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that if the merger were consummated, it would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, as well as Section 5 of the FTC Act. In accordance with Commission Rule 3.11(b)(4), the administrative complaint provides that the evidentiary hearing is scheduled to begin on May 10, 2016.

On April 22, 2016, Complaint Counsel and Respondents filed a Joint Expedited Motion (“Joint Motion”) seeking a 21-day continuance of the evidentiary hearing and related pre-hearing deadlines.¹ The parties represent that the district court recently concluded its hearing on the Commission’s motion for preliminary injunction under 15 U.S.C. § 53(b) in *FTC v. Staples, Inc.*, No. 1:15-cv-02115 (EGS) (D.D.C.) and that the court has committed to issue its order on the motion by May 10. Respondents further represent that if the district court grants the preliminary injunction motion, they will abandon the proposed transaction. If the district court denies the motion, Respondents

¹ Although the parties have styled their Joint Motion as one seeking a 21-day *stay* of administrative proceedings, the substance of their request makes clear they seek a 21-day continuance of the evidentiary hearing, which we have the authority to grant under Commission Rule 3.41(b). 16 C.F.R. § 3.41(b) (“The Commission, upon a showing of good cause, may order a later date for the evidentiary hearing to commence . . .”).

Interlocutory Orders, Etc.

assert they will file a motion pursuant to Commission Rule 3.26, which would trigger either a possible withdrawal of this matter from adjudication or a stay, pending further action by the Commission.

In light of the foregoing, the parties argue there is good cause for the Commission to continue the administrative proceedings for 21 days. Specifically, they contend that, should the evidentiary hearing become moot, the requested continuance could relieve third parties of the burden and cost associated with preparing witnesses to testify and filing motions for *in camera* treatment of their confidential materials, which would need to start happening soon under the current schedule. The parties also argue that a continuance would not prejudice the Commission, even if the adjudication of this matter were to proceed.

Although the Commission is committed to moving forward as expeditiously as possible with adjudicative proceedings,² we find there is good cause here to grant the requested continuance given the possibility that the evidentiary hearing may be rendered moot. We also find that a modest delay in the start of the hearing would not harm the Commission or the public interest, should it be necessary for the adjudication to go forward. Accordingly, we hereby grant the parties' request to continue the evidentiary hearing and all related pre-hearing deadlines by 21 days.

IT IS HEREBY ORDERED that the evidentiary hearing shall commence on May 31, 2016 and all related pre-hearing deadlines shall be extended by 21 days.

By the Commission.

² See Commission Rule 3.1, 16 C.F.R. § 3.1 (“[T]he Commission’s policy is to conduct [adjudicative] proceedings expeditiously.”); Commission Rule 3.41(b), 16 C.F.R. § 3.41(b) (“Hearings shall proceed with all reasonable expedition . . .”).

Interlocutory Orders, Etc,

IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, May 6, 2016

Order granting a Joint Expedited Motion seeking a 22-day continuance of the administrative hearing and related pre-hearing deadlines.

ORDER GRANTING CONTINUANCE

On December 17, 2015, the Commission issued an administrative complaint alleging that an affiliation agreement by the Respondents violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act. On December 21, 2015, pursuant to Section 13(b) of the FTC Act and Section 16 of the Clayton Act, the Commission filed a complaint in United States District Court for the Northern District of Illinois seeking a temporary restraining order and a preliminary injunction to prevent Respondents from consummating their proposed merger until final resolution of this administrative proceeding. Compl., *FTC v. Advocate Health Care Network*, No. 1:15-cv-11473 (N.D. Ill.) (Dec. 21, 2015). In accordance with Commission Rule 3.11(b) (4), the evidentiary hearing is scheduled to begin on May 24, 2016.

On March 18, 2016, the Commission denied without prejudice a motion by Respondents to stay the administrative hearing pending a ruling by the district court on the Commission's request for a preliminary injunction.¹ The parties have now filed a Joint Expedited Motion seeking a 22-day continuance of the

¹ *Advocate Health Care Network*, Docket No. 9369, Commission Order Denying Motion To Stay the Administrative Hearing (Mar. 18, 2016).

Interlocutory Orders, Etc.

administrative hearing and related pre-hearing deadlines,² citing the fact that the district court hearing on the Commission's motion for preliminary injunction has yet to conclude.³ Respondents represent that if the district court grants the preliminary injunction motion, they will abandon the proposed transaction. They further assert that, if the district court denies the preliminary injunction motion, they will file a motion pursuant to Commission Rule 3.26, which would trigger either a possible withdrawal of this matter from adjudication or a stay, pending further action by the Commission.

In support of their request for a continuance, the parties argue that, should the evidentiary hearing become moot, the requested continuance could relieve third parties of the burden and cost associated with preparing witnesses to testify and filing motions for *in camera* treatment of their confidential materials, which would need to commence soon under the current schedule. The parties also argue that a continuance would not prejudice the Commission, even if the adjudication of this matter were to proceed.

Although the Commission is committed to moving forward as expeditiously as possible with adjudicative proceedings,⁴ we find there is good cause here to grant the requested continuance of the administrative hearing and related deadlines. A short continuance would allow additional time for the district court to complete its proceeding and issue a ruling, which could obviate the need for an administrative hearing. Additionally, a short delay in the start of the administrative hearing would not harm the Commission or the

2 The parties have styled their Joint Motion as one seeking a stay of administrative proceedings, but their request makes clear that what they seek is a continuance of the evidentiary hearing and related deadlines, which we have the authority to grant under Commission Rule 3.41(b). 16 C.F.R. § 3.41(b) (“The Commission, upon a showing of good cause, may order a later date for the evidentiary hearing to commence . . .”).

3 The parties note that the evidentiary portion of the hearing will conclude on May 6, but that no date has been set for closing arguments.

4 See Commission Rule 3.1, 16 C.F.R. § 3.1 (“[T]he Commission’s policy is to conduct [adjudicative] proceedings expeditiously.”); Commission Rule 3.41(b), 16 C.F.R. § 3.41(b) (“Hearings shall proceed with all reasonable expedition . . .”).

Interlocutory Orders, Etc,

public interest should it be necessary for the administrative adjudication to go forward. We note, however, that a more significant delay may not be justified as our rules contemplate that both district court and administrative proceedings can proceed in parallel.

Accordingly, **IT IS HEREBY ORDERED** that the evidentiary hearing shall commence on June 15, 2016 and all related pre-hearing deadlines shall be extended by 22 days.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER
AND
PINNACLEHEALTH SYSTEM**

Docket No. 9368. Order, May 12, 2016

Order granting a Joint Expedited Motion for a Continuance of Administrative Proceedings, seeking a 21-day continuance of the administrative hearing and related pre-hearing deadlines.

ORDER GRANTING CONTINUANCE

On December 7, 2015, the Commission issued an administrative complaint alleging that an affiliation agreement by the Respondents violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act. On December 9, 2015, pursuant to Section 13(b) of the FTC Act and Section 16 of the Clayton Act, the Commission filed a complaint in United States District Court for the Middle District of Pennsylvania seeking a temporary restraining order and a preliminary injunction to prevent Respondents from consummating their proposed merger until final resolution of this administrative proceeding. Compl., *FTC v. Penn State Hershey Med. Ctr.*, No. 1:15-cv-2362-JEJ (M.D. Pa.) (Dec. 9, 2015). In accordance with Commission Rule 3.11(b) (4), the administrative complaint provides that the evidentiary hearing shall begin on May 17, 2016.

On March 21, 2016, the Commission denied without prejudice a motion by Respondents to stay the administrative hearing pending a ruling by the district court on the Commission's request for a preliminary injunction.¹ On May 4, 2016, the parties filed a Joint Expedited Motion for a Continuance of Administrative Proceedings, seeking a 21-day continuance of the administrative hearing and related pre-hearing deadlines. On May 9, 2016, the

¹ *Penn State Hershey Med. Ctr.*, Docket No. 9368, Commission Order Denying Motion To Stay the Administrative Hearing (Mar. 21, 2016).

Interlocutory Orders, Etc,

district court denied the Commission's request for a preliminary injunction.

In light of the district court's ruling, we find that there is good cause to grant a two-week continuance of the administrative hearing and related deadlines to allow the parties time to determine how to proceed and to make any motions before the Commission.

Accordingly, **IT IS HEREBY ORDERED** that the evidentiary hearing shall commence on June 1, 2016 and all related pre-hearing deadlines shall be extended by 14 days.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

LABMD, INC.

Docket No. 9357. Order, May 16, 2016

Order granting Complaint Counsel's unopposed Motion to correct the transcript of the Oral Argument held in this proceeding on March 8, 2016.

ORDER CORRECTING ORAL ARGUMENT TRANSCRIPT]

On May 4, 2016, Complaint Counsel filed an unopposed Motion to correct the transcript of the Oral Argument held in this proceeding on March 8, 2016. The Motion states that Complaint Counsel conferred with counsel for Respondent in a good faith effort to stipulate to the desired corrections, as prescribed by Commission Rule 3.52(i), 16 C.F.R. § 3.52(i), and that while Respondent has declined to join the Motion, Respondent agrees to the proposed corrections and will not oppose the Motion. Accordingly,

IT IS ORDERED THAT the Oral Argument Transcript be, and it hereby is, modified to adopt the two corrections requested by Complaint Counsel in the May 4 Motion, and to read as shown in the attached corrected copy.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER
AND
PINNACLEHEALTH SYSTEM***Docket No. 9368. Order, May 26, 2016*

Order granting a Joint Motion seeking to continue the hearing date to June 21, 2016, and all pre-hearing deadlines by 20 days.

ORDER GRANTING CONTINUANCE

The evidentiary hearing in this matter is scheduled to commence on June 1, 2016, following the grant of a prior continuance.¹ The parties now jointly request that the Commission continue the hearing date to June 21, 2016, and all pre-hearing deadlines by 20 days.

The pertinent facts are as follows. On May 9, 2016, the United States District Court for the Middle District of Pennsylvania denied the Commission's motion seeking a temporary restraining order and preliminary injunction to prevent Respondents from consummating their proposed merger until final resolution of this administrative proceeding.² On May 12, the Commission filed an emergency motion for an injunction pending appeal with the United States Court of Appeals for the Third Circuit, which was granted on May 24.

In their motion, the parties state that if, as has now occurred, the Third Circuit granted the Commission's emergency motion, the requested continuance would provide them with needed time to determine how to proceed in this administrative adjudication and whether to make any further motions before the Commission.

1 *Penn State Hershey Med. Ctr.*, Docket No. 9368, Commission Order Granting Continuance (May 12, 2016), <https://www.ftc.gov/system/files/documents/cases/160512pennstatehershey-order.pdf>.

2 Memorandum Opinion and Order, *FTC v. Penn State Hershey Med. Ctr.*, No. 1:15-cv-2362-JEJ (M.D. Pa.) (May 9, 2016).

Interlocutory Orders, Etc.

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence on June 21, 2016, and all related pre-hearing deadlines are extended by 20 days.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, June 2, 2016

Order granting a Joint Expedited Motion seeking an additional 26 days continuance of the administrative hearing and related pre-hearing deadlines.

ORDER GRANTING CONTINUANCE

The evidentiary hearing in this administrative proceeding is scheduled to commence on June 15, 2016, following the grant of a prior continuance to provide additional time for the U.S. District Court for the Northern District of Illinois to rule on the Commission's request for a preliminary injunction.¹ Although the preliminary injunction hearing has now concluded, the district court has taken the matter under advisement and has not indicated when it will issue a ruling. Citing this circumstance, Complaint Counsel and Respondents now request that the Commission continue the evidentiary hearing and all pre-hearing deadlines by an additional 26 days.²

Respondents reaffirm that if the district court grants the preliminary injunction motion, they will abandon the proposed transaction, and that if the preliminary injunction motion is denied, they will file a motion pursuant to Commission Rule 3.26, which would trigger either a possible withdrawal of this matter from adjudication or a stay, pending further action by the Commission. The parties also note that if the evidentiary hearing is to begin on June 15, trial preparations will require both the

¹ *Advocate Health Care Network*, Docket No. 9369, Commission Order Granting Continuance (May 6, 2016), <https://www.ftc.gov/system/files/documents/cases/160506advocateorder.pdf>.

² *Advocate Health Care Network*, Docket No. 9369, Joint Expedited Motion for Continuance of Administrative Proceedings (May 27, 2016).

Interlocutory Orders, Etc.

parties and numerous non-parties to expend significant resources over the next two weeks.

In light of the foregoing, we find there is good cause here to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence on July 11, 2016, and all related pre-hearing deadlines are extended by 26 days.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER
AND
PINNACLEHEALTH SYSTEM***Docket No. 9368. Order, June 10, 2016*

Order granting Complaint Counsel and Respondents' Joint Motion requesting that the Commission continue the hearing date until 21 days after the Third Circuit rules on the Commission's appeal and grant a corresponding extension of all pre-hearing deadlines.

ORDER GRANTING CONTINUANCE

The evidentiary hearing in this administrative proceeding is scheduled to commence on June 21, 2016, following the grant of a prior continuance. The Commission granted that continuance to enable Complaint Counsel and Respondents to determine how to proceed in this adjudication in light of developments in the companion federal court litigation.¹ In particular, the Commission appealed the federal district court's denial of the Commission's motion for a preliminary injunction to the U.S. Court of Appeals for the Third Circuit and sought an emergency injunction pending appeal. The Third Circuit granted the emergency injunction on May 24, 2016, and the appeal is pending.² Complaint Counsel and Respondents now jointly request that the Commission continue the hearing date until 21 days after the Third Circuit rules on the Commission's appeal and grant a corresponding extension of all pre-hearing deadlines.³

1 *Penn State Hershey Med. Ctr.*, Docket No. 9368, Commission Order Granting Continuance (May 26, 2016), <https://www.ftc.gov/system/files/documents/cases/160526pennstateorder.pdf>.

2 *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, No. 16-2365, Order (3d Cir. May 18, 2016).

3 *Penn State Hershey Med. Ctr.*, Docket No. 9368, Joint Expedited Motion for Continuance of the Administrative Hearing (May 27, 2016).

Interlocutory Orders, Etc.

Respondents state that, if the Third Circuit grants the Commission's appeal, they will abandon the merger and that, if the appeal is denied, they will file a motion pursuant to Commission Rule 3.26 to withdraw this matter from adjudication, pending further action by the Commission. The parties also note that, if the evidentiary hearing is to begin on June 21, trial preparations will require both the parties and numerous non-parties to expend significant resources over the next several weeks.

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence 21 days after the United States Court of Appeals for the Third Circuit renders its judgment on the Commission's appeal, and that all pre-hearing deadlines shall be extended until after the Court of Appeals renders its judgment, as determined by the Administrative Law Judge.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

LABMD, INC.

Docket No. 9357. Order, June 16, 2016

Order extending the time period for issuing the final Decision and Order in this Matter.

**ORDER EXTENDING TIME PERIOD FOR ISSUING FINAL DECISION
AND ORDER**

In order to give full consideration to the issues presented by the appeal in this proceeding, the Commission has determined, pursuant to Rule 4.3(b), 16 C.F.R. § 4.3(b), to extend the time period for issuing a final decision and order until July 28, 2016.

IT IS SO ORDERED.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

PROMEDICA HEALTH SYSTEM, INC.

Docket No. 9346. Order, June 24, 2016

Letter approving application for the spin-out of the St. Luke's Hospital Assets, re-establishing St. Luke's Hospital as an independent, standalone community hospital.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

Stephen Y. Wu, Esquire
McDermott Will & Emery LLP

Re: In the Matter of ProMedica Health System, Inc.
Docket No. 9346

Dear Mr. Wu:

This responds to the Application for Approval of Proposed Divestiture ("Application") to St. Luke's Holding Company, Inc., filed by ProMedica Health System, Inc. on April 25, 2016. Pursuant to the Final Order in Docket No. 9346 ("Order"), ProMedica requests Commission approval of its proposal to divest the assets required to be divested pursuant to the Order. The Application was placed on the public record for comments for thirty days, until June 2, 2016. Eight comments were received.

After consideration of the Application and other available information, the Commission has determined to approve the proposed divestiture to St. Luke's, as set forth in the Application. In according its approval, the Commission has relied upon the information submitted and the representations made by ProMedica and St. Luke's in connection with ProMedica's Application and has assumed them to be accurate and complete.

This also responds to ProMedica's Request for Extension of Time to Comply with the Final Order ("Request") filed on October 23, 2015 and its Addendum to Request for Extension of Time to Comply with the Final Order filed on March 31, 2016. Pursuant to Commission Rule 4.3(b), 16 C.F.R. § 4.3(b),

Interlocutory Orders, Etc,

ProMedica requests an extension of time in which to complete the divestiture required by the Order in this matter. Pursuant to the terms of the Order, ProMedica was required to complete the divestiture within one hundred eighty (180) days from the date the Order became final and effective, or by November 2, 2015. Rule 4.3(b) provides that “the Commission, for good cause shown, may extend any time limit prescribed by the rules in this chapter or order of the Commission.” Under applicable precedent, ProMedica has the burden of demonstrating good cause, and granting an extension of time rests in the discretion of the Commission. *United States v. Swingline, Inc.*, 371 F.Supp. 37, 45 (E.D.N.Y. 1974).

The Commission has reviewed this Petition, ProMedica’s compliance reports, and other information, and, after careful consideration, has determined to grant the Request and extend the time in which ProMedica must complete the divestiture to St. Luke’s as approved by the Commission today. ProMedica has shown that it began its effort immediately upon the Order becoming final and effective when the Supreme Court denied ProMedica’s petition for certiorari. ProMedica has remained in close communications with the Commission staff throughout its negotiations of a divestiture. ProMedica has shown that it has acted diligently throughout the divestiture period, that circumstances beyond its control are responsible for the delays, and that the delays in completing negotiations were not due to unreasonable demands or other conduct of ProMedica. Commission staff also believes that the additional time to reach an agreement with St. Luke’s was necessary to St. Luke’s due diligence and enabled St. Luke’s to acquire the divested assets with confidence of its future success. The Commission expects that ProMedica will complete the divestiture promptly upon the Commission’s approval.

By direction of the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, June 28, 2016

Order granting a Joint Expedited Motion seeking an additional 26 days continuance of the administrative hearing and related pre-hearing deadlines.

ORDER GRANTING CONTINUANCE

The evidentiary hearing in this administrative proceeding is scheduled to commence on July 11, 2016, following the grant of a prior continuance.¹ On June 14, 2016, the United States District Court for the Northern District of Illinois issued a memorandum opinion and order denying the Commission's request for preliminary injunctive relief.² The Commission then filed a notice of appeal with the United States Court of Appeals for the Seventh Circuit. On June 16, 2016, the Commission filed a Motion for Injunction Pending Appeal with the district court, which the district court granted. Complaint Counsel and Respondents now jointly request that the Commission stay the administrative proceedings until after the Seventh Circuit rules on the Commission's appeal, and grant a corresponding extension of all pre-hearing deadlines.³

Respondents state that if the Seventh Circuit grants the Commission's appeal, they will abandon the proposed transaction,

1 Commission Order Granting Continuance, *Advocate Health Care Network*, Docket No. 9369 (June 2, 2016), <https://www.ftc.gov/system/files/documents/cases/160602advocatehealthorder.pdf>.

2Memorandum Opinion & Order, *FTC v. Advocate Health Care Network*, No. 1:15-cv-11473 (N.D. Ill. June 14, 2016).

3 Joint Expedited Motion for Continuance of Administrative Proceedings, *Advocate Health Care Network*, Docket No. 9369, (June 24, 2016), <https://www.ftc.gov/system/files/documents/cases/160624advhcnmtn.pdf>.

Interlocutory Orders, Etc,

and that if the appeal is denied, they will file a motion pursuant to Commission Rule 3.26 to withdraw this matter from adjudication, pending further action by the Commission. The parties also note that if the evidentiary hearing is to begin on July 11, trial preparations will require both the parties and numerous non-parties to expend significant resources over the next two weeks.

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence 21 days after the United States Court of Appeals for the Seventh Circuit renders its judgment on the Commission's appeal, and that all pre-hearing deadlines shall be extended until after the Court of Appeals renders its judgment, as determined by the Administrative Law Judge.

By the Commission.

RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

THE ROBERT LARSON AUTOMOTIVE GROUP, INC. D/B/A LARSON VOLKSWAGEN AND AUDI TACOMA

FTC File No. 162 3006 – Decision, February 25, 2016

RESPONSE TO THE ROBERT LARSON AUTOMOTIVE
GROUP, INC.’S PETITION TO STRIKE OR LIMIT A CIVIL
INVESTIGATIVE DEMAND DATED DECEMBER 8, 2015

By McSWEENEY, Commissioner:

The Robert Larson Automotive Group, Inc. (“RLAG” or “Petitioner”), has filed a petition to strike or limit a civil investigative demand (“CID”) issued by the Commission on December 8, 2015. For the reasons stated below, the petition to strike or limit (“Petition”) is denied. Nonetheless, in order to expedite compliance in aid of the Commission’s investigation, the Commission incorporates certain modifications to the CID agreed to by staff and directs Petitioner to comply with the amended CID.

I. BACKGROUND

Volkswagen AG and Audi AG (hereinafter referred to collectively as “VW”) marketed certain 2009-2016 model year vehicles as low emission “Clean Diesel” vehicles that complied with federal emission standards. In 2014, state and federal agencies started to question the manufacturers’ claims for these vehicles. Most recently, the Justice Department, on behalf of the Environmental Protection Agency, sued VW alleging that more than 500,000 of these “Clean Diesel” vehicles contained “defeat devices” designed to mislead federal emissions tests.¹ The

¹ *United States v. Volkswagen AG, et al.*, No. 2:16-CV-10006 (E.D. Mich. Jan. 4, 2016). The EPA’s complaint was transferred to the Northern District of California to be considered as part of the related Multidistrict Litigation. *See in*

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complaint in that case alleges that these “defeat devices” can detect whether a vehicle is undergoing an emissions test and cause the vehicles to produce compliant emissions results, thus concealing the actual level of nitrogen oxide emissions they emit during normal operations.²

The Commission opened its own investigation of VW’s environmental claims after reviewing the marketing materials for these vehicles. As part of the investigation, the Commission issued CIDs to Volkswagen USA (“VW USA”) and to various third parties, including a number of car dealerships.³ On December 8, 2015, the Commission issued a CID to RLAG seeking, among other things, documents and information regarding the environmental claims for “Clean Diesel” vehicles, complaints about those claims, and certain information about sales and leased vehicles. Of particular relevance here, the CID requested information and materials regarding, with respect to the Clean Diesel vehicles, the results of any investigations or testing of the “defeat devices,” emissions, and the use of Diesel Exhaust Fluid to reduce nitrogen oxide emissions.

re: Volkswagen “Clean Diesel” Marketing, Sales Practices & Products Liability Litig., No. 3:15-md-02672 (N.D. Cal.).

² See *id.*, Complaint, ¶¶ 56-84.

³ The Commission’s Resolution Directing Use of Compulsory Process in a Non-Public Investigation of Unnamed Marketers Making Environmental Claims, describes the nature and scope of the investigation as follows:

To determine whether unnamed persons, partnerships, corporations, or others have been or are engaged in unfair or deceptive acts or practices, in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended, by: (1) making express or implied claims that are inconsistent with the Commission’s Guides for the Use of Environmental Claims, 16 C.F.R. Part 260; or (2) otherwise making express or implied environmental claims. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or to others would be in the public interest.

Resolution File No. 0823151 (dated April 8, 2011).

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Petitioner made a limited production by the due date, but nonetheless filed the instant petition on January 14, 2016, asking the Commission to strike or limit the CID, principally on grounds of undue burden. For the reasons discussed below, Petitioner has not shown undue burden or any other ground that would warrant striking or modifying the CID.

II. ANALYSIS

FTC compulsory process is proper “if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant” to the investigation.⁴ Further, production must not be “unduly burdensome.”⁵ Petitioner argues that the CID is unduly burdensome, overbroad, vague, lacks sufficient confidentiality protections, and was directed to the wrong entity. None of these arguments has merit.

A. The Commission May Seek Relevant Information from Third Parties.

Petitioner contends first that it should be excused from complying with the CID because VW assertedly “has almost all the material information the FTC seeks.”⁶ Petitioner claims that it neither designs nor tests the cars it sells, that all technical information it possesses responsive to the CID it receives from manufacturers, and that it should only respond to a narrowed CID after VW makes its production.⁷

The Commission, however, is not required to exhaust its efforts to gather responsive materials from the target of an investigation before it may issue process to third parties.⁸ The

⁴ *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950).

⁵ *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing, *inter alia*, *FTC v. Texaco, Inc.*, 555 F.2d 862, 881(D.C. Cir. 1977)).

⁶ Pet. at 3.

⁷ Pet. at 1, 3; Pet. Ex. A. (Larson Decl.) ¶ 4.

⁸ See, e.g., *Gasoline Pricing Investig.*, 141 F.T.C. 498, 505, 2006 WL 6679070, at *4 (2006).

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Commission may issue a CID to “any person” it “has reason to believe” possesses information or documents “relevant” to a law enforcement investigation regarding unfair or deceptive trade practices.⁹ Indeed, an important and effective tool in investigations involves comparing information and materials obtained from targets with that obtained from third parties. Thus, even if Petitioner were correct that VW has “almost all the material information the FTC seeks,”¹⁰ that would not justify placing any limitation on the CID to Petitioner. In any event, a number of the CID specifications ask for information that is plainly available only from Petitioner.¹¹ In short, Petitioner is not relieved of its obligation to produce responsive materials.¹²

B. The CID Does Not Impose Undue Burden

Petitioner also argues that compliance with the CID would be unduly burdensome and expensive, and would result in the production of information with little probative value.¹³ The standard for assessing the burden imposed by agency investigative process is well established. Agency process is not unduly burdensome unless compliance threatens to seriously impair or unduly disrupt the normal operations of the recipient’s business.¹⁴

9 15 U.S.C. §§ 57b-1(a)(6), (c)(1).

10 *See* Pet. at 3.

11 *See, e.g.*, Exh. 1 to Pet. Exh. A (CID, Doc. Req. 9) (“All Documents Relating To any compensation, incentives, bonuses, repayment, or offsets You or any Volkswagen Affiliate has given (or promised to give) to owners or lessees of Covered Vehicles You sold or leased, since September 14, 2015.”).

12 Petitioner’s specific objections to Document Requests 2-9 and 11 and Interrogatories 1-9 are unfounded for the same reasons. *See* Pet. at 7-9. Petitioner must produce responsive materials and information in its possession, custody, or control regardless of its origin. If Petitioner does not have such material, *see, e.g.*, Pet. at 9 (specific objections to Interrogatories 6, 8), it should certify as much and produce what it has.

13 Pet. at 4-5.

14 *See, e.g., Invention Submission*, 965 F.2d at 1090 (citing *Texaco*, 555 F.2d at 882); *Maryland Cup*, 785 F.2d at 479; *In re FTC Line of Business Report Litig.*, 595 F.2d 685, 703 (D.C. Cir. 1978).

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This same standard applies to nonparties.¹⁵ The recipient bears the responsibility of showing that the burden of compliance is undue.¹⁶ The recipient of agency process must show the “measure of [its] grievance rather than [asking the court] to assume it,”¹⁷ with the recognition that “[s]ome burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency’s legitimate inquiry and the public interest.”¹⁸

Petitioner asserts that compliance with the CID would involve reviewing “every record in [its] archive,” consisting of “many thousands of documents,” of which “only a small percentage” would be responsive.¹⁹ Petitioner also asserts its “best estimate” is that compliance would require someone “three months working full time” to compile the requested information.²⁰

Mr. Larson’s affidavit, however, does not provide any basis for these projections, and fails to show that such a search would

15 See, e.g., *Commission Order Affirming June 18, 2012 Ruling Denying Petition of Samsung Telecommunications America, LLC to Limit Subpoena Duces Tecum*, File No. 111-0163 (September 7, 2012), <https://www.ftc.gov/enforcement/cases-proceedings/petitions-quash/google-inc> (investigative subpoena issued on nonparty) (citing *FTC v. Rockefeller*, 441 F. Supp. 234, 240-42 (S.D.N.Y. 1977)); see also *In the Matter of Evanston Northwestern Healthcare Corp.*, No. 9315, 2004 FTC LEXIS 179, at *5-6 (Sept. 28, 2004) (citation omitted) (process issued on nonparties in administrative adjudicative proceeding); *FTC v. Ernstthal*, Misc. No. 78-0064, 1978 WL 1375 (D.D.C. May 30, 1978, *aff’d*, 607 F.2d 488, 489 n.1 (D.C. Cir. 1979) (rejecting burden, definiteness, and relevance challenges to administrative subpoena issued on nonparty in adjudicative hearing particularly where identically-situated nonparties complied without difficulty).

16 *In the Matter of January 16, 2014 Civil Investigative Demand Issued to the College Network, Inc.*, File No. 1323236, 2014 FTC LEXIS 90, at *5 (April 21, 2014) (citing, *inter alia*, *Texaco*, 555 F.2d at 882).

17 *Morton Salt*, 338 U.S. at 654.

18 *Texaco*, 555 F.2d at 882.

19 See Pet. at 4-5; Pet. Exh. A. (Larson Decl.) ¶¶ 7, 8.

20 Pet. Exh. A (Larson Decl.) ¶ 10.

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substantially disrupt its operations.²¹ Some cost of complying with an investigation – even substantial outlays – is to be expected; the burden of that cost must be evaluated in relation to the size and complexity of a recipient’s business operations.²² Courts have found that agency process that requested far more documents than the CID at issue, and that imposed significant expenses, was not unduly burdensome.²³ Moreover, several CID requests have particular limitations on the scope of the response that lessen burden.²⁴

Petitioner argues further that the burden of compliance is far outweighed by the “negligible value” of some of the information requested.²⁵ In particular, Petitioner contends that information about the amount of diesel exhaust fluid (“DEF”) put in cars during servicing “adds nothing” to “admissions already made by Volkswagen.”²⁶ In fact, the amount of DEF that vehicles consumed could reflect important information about the functioning of the defeat device and who would have known about its existence. Regardless, “[t]he Commission has no

21 For similar reasons, we deny as unfounded Petitioner’s related objection that the deadline for compliance was “unreasonably short” because it would take “at least three months” to complete a review of responsive documents. Pet. at 4. In addition to extending Petitioner’s compliance date until January 14, 2016, see Pet. Ex. 3 to Ex. A, FTC staff offered to further extend the compliance date and proposed other modifications to reduce the claimed burden.

22 *The College Network*, 2014 FTC LEXIS 90, at *18.

23 See, e.g., *FDIC v. Garner*, 126 F.3d 1138, 1145-46 (9th Cir. 1997) (affirming enforcement of agency subpoena that recipient alleged demanded “over one million” documents from hospital); see also *FTC v. Jim Walter Corp.*, 651 F.2d 251, 258 (5th Cir. Unit A July 1981) (citing *California Bankers Ass’n v. Schultz*, 416 U.S. 21 (1974) (\$392,000 cost for a bank with net income of \$178 million)); *Texaco*, 555 F.2d at 922 (\$4,000,000).

24 For example, Document Request 1 requires only “[r]epresentative samples of” (not every document reflecting) certain advertisement claims, while Document Requests 5, 7, 8, 9, and Interrogatories 7 and 8 significantly limit the time period for responsive documents (from September 14, 2015 until compliance with the CID). See Exh. 1 to Pet. Exh. A.

25 Pet. at 5.

26 *Id.*

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obligation to establish precisely the relevance of the material it seeks in an investigative subpoena by tying that material to a particular theory of violation.”²⁷ The material “need only be relevant to the *investigation* [into a possible law violation] – the boundary of which may be defined quite generally.”²⁸ Indeed, the FTC’s “own appraisal of relevancy must be accepted so long as it is not ‘obviously wrong,’”²⁹ a showing Petitioner does not make here.³⁰

C. The CID is Not Overbroad

Petitioner argues that the definition of “Merchantability Claims” is overbroad because it would include any imported car beyond those at issue here.³¹ This claim is without merit. A CID request is overbroad only where it is “out of proportion to the ends sought,” and “of such a sweeping nature and so unrelated to the matter properly under inquiry as to exceed the investigatory power.”³² In fact, the term is used only in two document requests seeking marketing materials referring specifically to “Covered

27 *Invention Submission*, 965 F.2d at 1090 (citing *Texaco*, 555 F.2d at 877).

28 *Id.* (emphasis in original) (citations omitted); see also *FTC v. Church & Dwight Co., Inc.*, 747 F. Supp. 2d 3, 9 (D.D.C. 2010) (rejecting claim that the “FTC [must show] like any litigant, that the document demanded will lead to reasonably relevant and ultimately admissible evidence” as mischaracterizing the nature of the FTC’s investigative authority) (citing *Morton Salt*, 338 U.S. at 642 and *Texaco*, 555 F.2d at 874), *aff’d*, 665 F.3d 1312 (D.C. Cir. 2011).

29 *Invention Submission*, 965 F.2d at 1089 (citations omitted).

30 Petitioner’s specific objections to Document Request 11 and Interrogatory 9 regarding DEF, see Pet. at 8, 9, are unfounded for the same reasons. Those requests are not unduly burdensome and they are directly related to the April 8, 2011 Resolution regarding environmental claims. Also unfounded is Petitioner’s challenge on relevancy grounds to Document Request 10 (regarding franchise agreements between Petitioner and VW USA since 2008), see Pet. at 8, as those agreements could describe the role of the dealership in marketing vehicle environmental claims and are therefore central to the investigation.

31 Pet. at 6.

32 *U.S. v. Wyatt*, 637 F.2d 293, 302 (5th Cir. 1981) (quoting, *inter alia*, *Morton Salt*, 338 U.S. at 652).

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Vehicles” (certain 2009-2016 models of VWs and Audis at issue),³³ not any imported vehicle, and thus is sufficiently targeted to the investigation. Petitioner’s overbreadth challenges to other specific CID requests are likewise unfounded because they are all sufficiently narrow and focused on the subject matter of the investigation.³⁴

D. The CID Requests are Specific and Definite

Petitioner claims that the term “defeat device” is undefined and vague.³⁵ A CID request is impermissibly vague where it lacks reasonable specificity or is too indefinite to allow a responding party to comply.³⁶ The term “defeat device,” is in fact explained in the CID itself (under the definition of “Covered Vehicle”) as one “that causes, or may cause, the vehicle to produce materially different emissions during emissions testing than during normal road operation.”³⁷ The provided definition is sufficiently specific and focused on the agency’s investigation to enable Petitioner to identify responsive materials.³⁸

33 See Document Requests 1, 4; Exh. 1 to Pet. Exh. A (CID) at 2-5 (§ I. “Definitions” ¶¶ H and O).

34 For example, Petitioner challenges Document Request 1 claiming that it “would cover every advertisement which included a diesel vehicle,” Pet. at 7, whereas in fact the CID as written is limited to just “[r]epresentative samples of . . . Environmentally Friendly” or “Merchantability” claims for the 2009-2016 model vehicles at issue. Likewise, Document Request 2 (regarding substantiation that the relevant “Covered Vehicles” are “Environmentally Friendly”) and Request 4 (sales methods for “Covered Vehicles” relating to “Environmentally Friendly Claims”) are not impermissibly broad because they are narrowly tailored to the agency’s inquiry.

35 See Pet. at 6, 7 (objection to Document Request 5); Pet. Exh. A (Larson Decl.) ¶ 13.

36 See, e.g., *College Network*, 2014 FTC LEXIS 90, at *4 (citing, *inter alia*, *United States v. Fitch Oil Co.*, 676 F.2d 673, 679 (Temp. Emer. Ct. App. 1982)).

37 Exh. 1 to Pet. Exh. A (CID) at 2 (§ I. “Definitions” ¶ H).

38 For the same reasons, we conclude that Petitioner’s vagueness challenge to Document Request 2 (regarding substantiation that the relevant “Covered Vehicles” are “Environmentally Friendly”), *see* Pet. at 7, is unfounded as that request is adequately defined.

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E. The FTC Act and the Commission's Rules of Practice Protect Confidential Business and Customer Information

Petitioner objects that the CID improperly asks for confidential business and personal customer information without sufficient protections, and in particular complains about information that may be shared with “other unnamed agencies without restriction.”³⁹ This claim too has no merit. The Commission’s Rules of Practice and relevant statutory provisions provide ample protection for documents and information obtained by the Commission through compulsory process.⁴⁰ Courts have consistently held that these provisions provide adequate protection and that the Commission has a full right to access even the most highly sensitive information, including trade secrets.⁴¹ These protections apply to proprietary business and sensitive customer information like that called for by the FTC’s requests. Additionally, under the relevant legal provisions, the Commission is permitted to share information obtained through process with other government agencies, provided those agencies describe the nature of their law enforcement activity, state the relevance of the requested information, and ensure that such information will be maintained in confidence and will be used only for official law enforcement purposes.⁴²

39 Pet. at 6-7; Pet. Exh. A. (Larson Decl.) ¶ 14.

40 See 15 U.S.C. §§ 46(f), 57b-2; 16 C.F.R. § 4.10(a).

41 See, e.g., *FTC v. Invention Submission Corp.*, No. 89-272, 1991 WL 47104, at *4 (D.D.C. 1991), *aff’d*, 965 F.2d 1086, 1089 (D.C. Cir. 1992); *In re Subpoena Duces Tecum*, 228 F.3d 341, 351 (4th Cir. 2000) (enforcing subpoena requesting sensitive health care information in light of statutory protections).

42 See 15 U.S.C. § 46(f); 16 C.F.R. § 4.11(c) and (j).

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F. Petitioner Had Adequate Notice of the CID Requests

Finally, Petitioner contends that the CID should be quashed because it was directed to an affiliated entity that does not directly sell Volkswagens. We disagree.

The Commission issued the CID to “The Robert Larson Automotive Group, Inc., also d/b/a Larson Volkswagen and Audi Tacoma,” and directed it to the attention of “Robert Larson, President.”⁴³ Petitioner contends that “The Robert Larson Automotive Group, Inc.” does not sell VWs and that the CID should have been directed instead to Larson Motors, Inc., which does.⁴⁴

There is no dispute, however, that Robert Larson is the President, CEO, and owner of both RLAG and Larson Motors.⁴⁵ Petitioner does not allege that it was misled or prejudiced in any way by what is at most a technical flaw.⁴⁶ Indeed, the registered agent responsible under Washington state law for receiving service of process for Larson Motors is located at the same address in Tacoma, Washington as RLAG’s business address.

43 Exh. 1 (CID) to Pet. Exh. A.

44 Pet. at 3; Pet. Exh. A (Larson Aff.) ¶¶ 2, 3.

45 See, e.g., Pet. Exh. A (Larson Aff.) ¶ 1.

46 See, e.g., [Morrel v. Nationwide Mut. Fire Ins. Co.](#), 188 F.3d 218, 223-24 (4th Cir. 1999) (excusing notice that named improper party “in such terms that every intelligent person understands who is meant ... the misnomer of a corporation in a notice, summons ... or other step in a judicial proceeding is immaterial if it appears that [the corporation] could not have been, or was not, misled,” where President of the intended recipient received service, and document itself made clear the intended recipient) (citation omitted); *Nader v. Fed. Election Comm’n*, 823 F. Supp. 2d 53, 67-68 (D.D.C. 2011) (failure to notice respondents of administrative complaint filed against them constituted harmless error), *appeal dismissed*, 725 F.3d 226 (D.C. Cir. 2013); *FEC v. Club for Growth, Inc.*, 432 F.Supp. 2d 87, 90 (D.D.C. 2006) (defect in notice of complaint constituted harmless error where notice was sent to similar sounding entity and officer of both entities “surely had coterminous notice”) (citation omitted); [SEC v. Lines Overseas Mgmt., Ltd., No. Civ. A. 04-302, 2005 WL 3627141, at *10 \(D.D.C. Jan. 7, 2005\)](#) (subpoena issued to “LOM Group of Companies,” rather than target company “LOM, Ltd.,” was enforced because the intended recipient was “plainly obvious.”).

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Further, Petitioner's counsel contacted FTC staff on December 15, 2015 – the day after the CID was delivered by FedEx at that Tacoma address – to discuss Petitioner's compliance.

In sum, we conclude that Petitioner's challenges to the CID are unfounded and deny its Petition.

III. MODIFICATION OF THE CID

While we deny the Petition as lacking merit, we note that Commission staff offered certain modifications to the CID in the interests of expedition. The CID is hereby modified in accordance with the offer that staff made to Petitioner by email dated January 13, 2016.

IV. CONCLUSION

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Petition of The Robert Larson Automotive Group, Inc., also d/b/a Larson Volkswagen and Audi Tacoma, to Strike or Limit the Civil Investigative Demand be, and it hereby is, **DENIED**, and

IT IS FURTHER ORDERED THAT Petitioner The Robert Larson Automotive Group, Inc., also d/b/a Larson Volkswagen and Audi Tacoma, shall comply with the Commission's CID **as modified herein** on or before March 15, 2016.

By the Commission.

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