

## Complaint

## IN THE MATTER OF

**HIKMA PHARMACEUTICALS PLC**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-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

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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:

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- 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

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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

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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

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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 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.

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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.

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- 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.

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**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:

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- 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

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- 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

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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;

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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 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

## Order to Maintain Assets

- 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

## Order to Maintain Assets

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”):

## Decision and 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 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:

## Decision and Order

- 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.

## Decision and Order

- 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” (“SND A”), 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

## Decision and Order

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;

## Decision and Order

- 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,

## Decision and Order

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:

## Decision and Order

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.

## Decision and Order

- 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, 1<sup>st</sup> 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 Flecaidine 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 Flecaidine 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

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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

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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

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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,

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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.

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**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