

Complaint

IN THE MATTER OF

**HIKMA PHARMACEUTICALS PLC,
AND
C.H. BOEHRINGER SOHN AG & CO. KG**

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

*Docket No. C-4572; File No. 151 0044
Complaint, March 28, 2016 – Decision, March 28, 2016*

This consent order addresses the \$5 million acquisition by Hikma Pharmaceuticals PLC of certain assets of Ben Venue Laboratories, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening future competition in the markets for acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection in the United States. The consent order requires Hikma to divest the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection to Amphastar Pharmaceuticals, Inc.

Participants

For the *Commission*: Sebastian A. Lorigo.

For the *Respondents*: Jonathan I. Gleklen and Peter J. Levitas, Arnold & Porter LLP; Keira Campbell and David P. Wales, Jones Day.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Hikma Pharmaceuticals PLC (“Hikma”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets of Ben Venue Laboratories Inc., a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG (collectively “Boehringer”) (Hikma and Boehringer hereinafter collectively referred to as

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“Respondents”), entities subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales, with its corporate office and principal place of business located at 13 Hanover Square, London, W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o: West-Ward Pharmaceuticals, 401 Industrial Way West, Eatontown, NJ 07724.

2. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany with its principal executive offices located at Binger Strasse 173, 55216 Ingelheim, Germany and its United States address for service of process and the Complaint and Decision and Order, as follows: Corporate Secretary, 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Under the terms of a Sale and Purchase Agreement with an effective date of December 4, 2014 (“Agreement”), Hikma proposes to acquire certain assets for approximately \$5 million

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from Boehringer (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT PRODUCT MARKETS

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

- a. acyclovir sodium injection;
- b. diltiazem hydrochloride injection;
- c. famotidine injection;
- d. prochlorperazine edisylate injection; and
- e. valproate sodium injection.

IV. THE RELEVANT GEOGRAPHIC MARKET

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

V. THE STRUCTURE OF THE MARKETS

7. Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. Three firms, Boehringer, Fresenius Kabi AG (“Fresenius”), and AuroMedics Pharma LLC (“AuroMedics”), currently have Abbreviated New Drug Applications (“ANDAs”) for this drug that have been approved by the U.S. Food and Drug Administration (“FDA”). Only Fresenius and AuroMedics currently supply acyclovir sodium injection to the market. Hikma and one other firm are likely to enter the market in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of acyclovir sodium injection from five to four.

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8. Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. There are four firms that currently have FDA-approved ANDAs for diltiazem hydrochloride injection, Hikma, Boehringer, Hospira, Inc. (“Hospira”), and Akorn, Inc. (“Akorn”), but only Hikma, Hospira, and Akorn currently supply the market. No other firms are likely to enter the market in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.

9. Famotidine injection treats ulcers and gastroesophageal reflux disease. Three firms currently sell the vial presentation of famotidine injection, Hikma, Fresenius, and Mylan N.V. (“Mylan”). Boehringer has an FDA-approved ANDA for famotidine injection vials, but had no sales of the drug in 2014. No other companies have FDA-approved ANDAs for famotidine injection vials. The Acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.

10. Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. Since that time, Heritage Pharmaceuticals Inc. (“Heritage”) has assumed all sales of prochlorperazine edisylate injection. Hikma is the only other company that has an FDA-approved ANDA for prochlorperazine edisylate injection, but it is not currently supplying the market. Another firm has prochlorperazine edisylate injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.

11. Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. There are two firms that currently supply valproate sodium injection in the market, Hikma and Fresenius. Boehringer has an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm has valproate sodium injection in its development pipeline and anticipates achieving

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FDA approval of its ANDA in the near future. Thus, the Acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

VI. EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating future competition between Hikma and the Boehringer assets and reducing the number of generic competitors in the markets for (1) acyclovir sodium injection; (2) diltiazem hydrochloride injection; (3) famotidine injection; (4) prochlorperazine edisylate injection; and (5) valproate sodium injection, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VII. ENTRY CONDITIONS

13. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. Although a limited number of firms other than Respondents plan to begin competing in some relevant markets in the future, such entry would not be sufficient to prevent the competitive harm likely to result from the Acquisition. In addition, no other entry is likely to occur for a substantial amount of time that would eliminate the price increases that will occur after consummation of the Acquisition.

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VIII. VIOLATIONS CHARGED

14. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

15. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of March, 2016, issues its Complaint against said Respondents.

By the Commission, Commissioner Brill not participating.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Hikma Pharmaceuticals PLC (“Hikma”) of certain assets owned by Ben Venue Laboratories, LLC (as successor to Ben Venue Laboratories, Inc.), a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG (collectively “Boehringer”) (Hikma and Boehringer hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent Hikma is a corporation organized, existing and doing business under and by virtue of the laws of England and Wales with its principle executive offices located at 13 Hanover Square, London W1S 1HW, United Kingdom and its United States address for service of process and the Complaint and Decision and Order, as follows: General Counsel, Hikma Pharmaceuticals PLC, c/o: West-Ward Pharmaceuticals, 401 Industrial Way West, Eatontown, NJ 07724.
2. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany with its principle executive offices located at Binger Strasse 173, 55216 Ingelheim, Germany and its United States address for service of process and the Complaint and Decision and Order, as follows:

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Corporate Secretary, 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. The Commission has jurisdiction over the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**I.**

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

- A. “Hikma” means Hikma Pharmaceuticals, PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Hikma Pharmaceuticals, PLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Hikma shall own the Transferred Assets.
- B. “Boehringer” means C.H. Boehringer Sohn AG & Co. KG its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by C.H. Boehringer Sohn AG & Co. KG (including without limitation, Ben Venue Laboratories, Inc. and Boehringer Ingelheim Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Hikma and Boehringer, individually and collectively.
- D. “Commission” means the Federal Trade Commission.

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- E. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Hikma’s acquisition of certain assets of Respondent Boehringer pursuant to the Acquisition Agreement.
- G. “Acquisition Agreement” means the *Asset Purchase Agreement* dated December 4, 2014, by and among Ben Venue Laboratories, LLC (as successor to Ben Venue Laboratories, Inc.), Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals PLC, to effect the Acquisition among Hikma and Boehringer that was submitted to the Commission.
- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Acyclovir Sodium Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 074596, and any supplements, amendments, or revisions thereto.
- J. “Acyclovir Sodium Injection Product Assets” means all rights, title and interest in and to all assets related to

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the Business of Respondent Boehringer within the Geographic Territory related to each of the Acyclovir Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acyclovir Sodium Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.

- K. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- L. “Amphastar” means Amphastar Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware with its principal executive offices located at 11570 6th Street, Rancho Cucamonga, CA 91730.
- M. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“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. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to

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21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

- N. “Boehringer Transferred Assets” means the Transferred Assets that are included in the assets to be transferred by Ben Venue Laboratories, LLC to Respondent Hikma pursuant to the Acquisition Agreement.
- O. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.
- P. “Categorized Assets” means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondents sign the Agreement Containing Consent Order in this matter and as are maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date for each Divestiture Product:
 - 1. all rights to all of the Applications related to the specified Divestiture Product;
 - 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 - 3. all Product Approvals related to the specified Divestiture Product;
 - 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

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

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notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

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

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specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

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

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14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
15. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
16. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
17. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
18. all of the Respondents' books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent

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structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

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

- Q. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- R. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

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- S. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- T. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- U. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage

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manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- V. “Diltiazem Hydrochloride Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 074617, and any supplements, amendments, or revisions thereto.
- W. “Diltiazem Hydrochloride Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Diltiazem Hydrochloride Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Diltiazem Hydrochloride Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- X. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

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

Y. “Divestiture Agreements” means the following:

1. *Asset Purchase Agreement* by and between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc., dated as of March 4, 2016, and
2. All amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Divestiture Agreements are the means by which Hikma proposes to divest, transfer, and otherwise convey the Transferred Assets, including the Divestiture Product Assets, to Amphastar, and are contained in Non-Public Appendix I. The Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

Z. “Divestiture Product(s)” means the following, individually and collectively:

1. Acyclovir Sodium Injection Products;
2. Diltiazem Hydrochloride Injection Products;
3. Famotidine Injection Products;
4. Prochlorperazine Edisylate Injection Products;

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5. Valproate Sodium Injection Products.

AA. “Divestiture Product Assets” means the following, individually and collectively:

1. Acyclovir Sodium Injection Product Assets;
2. Diltiazem Hydrochloride Injection Product Assets;
3. Famotidine Injection Product Assets;
4. Prochlorperazine Edisylate Injection Product Assets;
5. Valproate Sodium Injection Product Assets.

BB. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondents:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
4. to have the specified Divestiture Product(s) made anywhere in the World for distribution or sale

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within, or import into the Geographic Territory;
and

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

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

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- GG. “Famotidine Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No.’s 075825, 075684, 075622, and 075651, and any supplements, amendments, or revisions thereto.
- HH. “Famotidine Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Famotidine Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Famotidine Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- II. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions.
- JJ. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- KK. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from a Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter

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that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

- LL. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- MM. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- NN. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order.
- OO. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- PP. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- QQ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

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- RR. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- SS. “Prochlorperazine Edisylate Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 040540, and any supplements, amendments, or revisions thereto.
- TT. “Prochlorperazine Edisylate Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Prochlorperazine Edisylate Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Prochlorperazine Edisylate Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.
- UU. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- VV. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a

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Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

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

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

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

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the

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Respondents shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

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

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

YY. “Product Development Reports” means:

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

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

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17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

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

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

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Hikma”, or “Boehringer”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or

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general registered images or symbols by which Hikma, or Boehringer can be identified or defined.

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

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

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use in any Application related to that Divestiture Product.

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

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.

CCC. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*,

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detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

DDD. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

EEE. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

FFF. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.

GGG. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent(s) and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred,

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delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

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

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amendments, exhibits, attachments, agreements, and schedules thereto.

HHH. “Retained Product” means any Product(s) other than a Divestiture Product.

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

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

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified

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Divestiture Product that are acceptable to the Acquirer;

3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

KKK. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

LLL. "Third Party(ies)" means any non-governmental Person other than the following: the Respondents; or

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the Acquirer of particular assets or rights pursuant to this Order.

MMM. “Transferred Assets” means the Transferred Assets as defined in Section 1.02 of the *Asset Purchase Agreement* between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc., March 4, 2016. This *Asset Purchase Agreement* is a Divestiture Agreement and is attached to this Order in Non-Public Appendix I. The Transferred Assets include the Divestiture Product Assets.

NNN. “Valproate Sodium Injection Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned or controlled by Respondent Boehringer pursuant to ANDA No. 076295, and any supplements, amendments, or revisions thereto.

OOO. “Valproate Sodium Injection Product Assets” means all rights, title and interest in and to all assets related to the Business of Respondent Boehringer within the Geographic Territory related to each of the Valproate Sodium Injection Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Valproate Sodium Injection Products, as such assets and rights are in existence as of the date Respondents sign the Agreement Containing Consent Order in this matter and as are required to be maintained by the Respondents in accordance with the terms of the Agreement Containing Consent Order and this Order until the Closing Date.

PPP. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such

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Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

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

- A. Not later than ten (10) days after the Acquisition Date, Respondent Hikma shall divest the Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Amphastar, pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Amphastar, or to reduce any obligations of Respondents, under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

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

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provided further, however, that if Respondent Hikma has divested the Divestiture Product Assets to Amphastar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Hikma, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets to Amphastar (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date for each respective Divestiture Product, Respondent Hikma shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by the Acquirer for the purposes of the Acquirer determining whether to assume such contracts or agreements.
- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent Hikma to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

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

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

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- b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 - 5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent who provide assistance to an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 - 6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.
- E. Upon reasonable written notice and request from the Acquirer, Respondent Hikma shall provide, or cause to be provided to the Acquirer in a manner consistent with the Technology Transfer Standards the following:
- 1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 - 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products.

Respondent Hikma shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a

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

- F. Respondent Hikma shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- G. Not later than thirty (30) days after the Closing Date, Respondent Hikma shall provide written notification of the restrictions on the use and disclosure of the

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Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- H. Respondent Boehringer shall ensure that the Boehringer Transferred Assets are provided to Respondent Hikma without disruption or delay pursuant to the Acquisition Agreement, and, until Respondent Boehringer completely transfers and delivers such Boehringer Transferred Assets to Respondent Hikma, Respondent Boehringer shall:
1. prevent the destruction, removal, wasting, deterioration, or impairment of the Boehringer Transferred Assets;
 2. not sell, transfer, encumber or otherwise impair the Boehringer Transferred Assets (other than as is contemplated by the Acquisition Agreement); and
 3. not take any action that lessens the full economic viability, marketability, or competitiveness of the Boehringer Transferred Assets.

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provided, however, Respondent Boehringer has no obligation hereunder with respect to any Transferred Assets, Divestiture Product Assets, or Categorized Assets other than the Boehringer Transferred Assets.

- I. Until Respondent Hikma divests the Divestiture Product Assets to an Acquirer, Respondent Hikma shall:
 1. prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Product Assets;
 2. not sell, transfer, encumber or otherwise impair the Divestiture Product Assets; and
 3. not take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Product Assets.
- J. Respondent Hikma shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:
 1. any Patent owned by or licensed to Respondent Hikma as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;
 2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to Respondent Hikma at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

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

- K. Upon reasonable written notice and request from an Acquirer to Respondent Hikma, Respondent Hikma shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Hikma to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the

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Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

- L. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), that Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent

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that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent's outside counsel related to that Divestiture Product.
- M. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
 2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Agreement Containing Consent Order, and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Hikma, which consent shall

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

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

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

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

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Hikma's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Order.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondent Hikma, on such reasonable and customary terms and conditions as the

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

- G. Respondent Hikma shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondent Hikma shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

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- I. Respondent Hikma may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, maintain, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, remediate, divest, transfer, deliver or otherwise convey these assets in a

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manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, remediate, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph,

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Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

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

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amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of

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

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such

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

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

V.

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

- A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain

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regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

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

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

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent Hikma shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial

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purposes thereof, and provisions to reflect the full scope and breadth of Respondent's obligation to the Acquirer pursuant to this Order.

- D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

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

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C., II.D., II.G., II.H., and II.I, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this

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Order to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

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

VIII.

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

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

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IX.

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

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on March 28, 2026.

By the Commission, Commissioner Brill not participating.

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX I

Asset Purchase Agreement by and between Hikma Pharmaceuticals PLC and Amphastar Pharmaceuticals, Inc. dated March 4, 2016.

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

NON-PUBLIC APPENDIX II

Asset Purchase Agreement among Ben Venue Laboratories, Inc., Boehringer Ingelheim Corporation, and Hikma Pharmaceuticals, dated December 4, 2014.

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

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Hikma Pharmaceuticals PLC (“Hikma”) and C.H. Boehringer Sohn AG & Co. KG (“Boehringer”) that is designed to remedy the anticompetitive effects that otherwise would have resulted from Hikma’s proposed acquisition of forty-nine Abbreviated New Drug Applications (“ANDAs”) from Ben Venue Laboratories,

Analysis to Aid Public Comment

Inc. (“Ben Venue”), a subsidiary of Boehringer, in five generic injectable pharmaceutical markets. Boehringer recently exited the markets related to these ANDAs when it ceased its manufacturing and other operations through Ben Venue. Under the terms of the proposed Consent Agreement, Hikma is required to divest to Amphastar Pharmaceuticals, Inc. (“Amphastar”) the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection.

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

Pursuant to a Sale and Purchase Agreement dated December 4, 2014 (“Proposed Acquisition”), Hikma proposes to acquire forty-nine ANDAs from Boehringer for approximately \$5 million. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening future competition in the markets for acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection in the United States. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

I. The Relevant Products and Structure of the Markets

The relevant products are all generic versions of injectable pharmaceutical products. Generic versions of these products are usually launched after a branded product’s patents expire, or a

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generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. Sometimes, however, a branded injectable drug manufacturer may choose to lower its price and compete against generic versions of the drug, in which case it would be a participant in the generic drug market.

The relevant products at issue and the structure of each of the relevant markets is as follows:

- Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. Three firms, Boehringer, Fresenius Kabi AG (“Fresenius”), and AuroMedics Pharma LLC (“AuroMedics”), currently have ANDAs for this drug that have been approved by the U.S. Food and Drug Administration (“FDA”). Only Fresenius and AuroMedics currently supply acyclovir sodium injection to the market. Hikma and one other firm are likely to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of acyclovir sodium injection from five to four.
- Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. There are four firms that currently have FDA-approved ANDAs for diltiazem hydrochloride injection, Hikma, Boehringer, Hospira, Inc. (“Hospira”), and Akorn, Inc. (“Akorn”), but only Hikma, Hospira, and Akorn currently supply the market. No other firms are likely to enter the market in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.

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- Famotidine injection treats ulcers and gastroesophageal reflux disease. Three firms currently sell the vial presentation of famotidine injection, Hikma, Fresenius, and Mylan N.V. Boehringer has an FDA-approved ANDA for famotidine injection vials, but had no sales of the drug in 2014. No other companies appear to be poised to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.
- Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. Since that time, Heritage Pharmaceuticals Inc. has assumed all sales of prochlorperazine edisylate injection. Hikma is the only other company that has an FDA-approved ANDA for prochlorperazine edisylate injection, but it is not currently supplying the market. Another firm has prochlorperazine edisylate injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.
- Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. There are two firms that currently supply valproate sodium injection in the market, Hikma and Fresenius. Boehringer has an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm has valproate sodium injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

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II. Competitive Effects

The transaction will reduce competition by decreasing the number of future suppliers in each of these markets; in generic pharmaceutical products, prices generally decrease as the number of competing generic suppliers increases. In addition, the injectable pharmaceutical industry generally, and the generic products at issue in this investigation in particular, are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities of, and contributed to price increases of, several of the generic injectable products impacted by this transaction. By reducing the number of likely future competitors in these markets, the Proposed Acquisition will likely create a direct and substantial anticompetitive effect on prices for each of the relevant products, absent the remedies required by the proposed Consent Agreement.

In each of the relevant markets, either Hikma or Boehringer, or both, currently do not supply an existing generic product. For markets in which Hikma is not a current competitor, it is likely to become one in the near future. Boehringer has recently exited each of these markets, but, absent the Proposed Acquisition, it would have had the incentive to sell these ANDAs to a third-party supplier who would likely bring these products to market. Hikma, which already has an approved ANDA or is likely to soon achieve FDA approval for an ANDA in each of the five relevant markets at issue, lacks that incentive, and thus, customers would be deprived of the price decreases that likely would have accompanied third-party entry into each of these concentrated markets.

III. Entry

Entry into each of these generic injectable product markets will not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years.

Analysis to Aid Public Comment

IV. The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Hikma is required to divest the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection to Amphastar. Hikma must accomplish these divestitures and relinquish its rights no later than ten days after the acquisition.

Amphastar is a global pharmaceutical company based in Rancho Cucamonga, California and has over 1,200 employees worldwide. The company owns five pharmaceutical manufacturing facilities and produces a variety of branded and generic pharmaceutical products. Amphastar manufactures and sells sixteen injectable drug products in the United States, as well as a broad range of other pharmaceutical dosage formulations, including emulsions, suspensions, jellies, and lyophilized products. The company sells most of its products through long-standing relationships with major group purchasing organizations, drug wholesalers, and retailers in the United States. With its experience in generic markets, and in injectable products in particular, Amphastar is expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Amphastar is not an acceptable acquirer, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Amphastar and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The

Analysis to Aid Public Comment

Order requires Boehringer to maintain the economic viability, marketability, and competitiveness of the assets to be divested until they are transferred to Hikma, and requires Hikma to do the same until such time as they are transferred to a Commission-approved acquirer. The Order also requires that the parties transfer all confidential business information, regulatory, formulation, and manufacturing reports, as well as provide access to employees who possess or are able to identify such information. Because the products related to the Boehringer (Ben Venue) ANDA assets have already exited the market, the Order does not require a transitional supply agreement.

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

Complaint

IN THE MATTER OF

**GENERAL WORKINGS INC. D/B/A VULCUN,
ALI MOIZ
AND
MURTAZA HUSSAIN**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4573; File No. 152 3159
Complaint, April 18, 2016 – Decision, April 18, 2016*

This consent order addresses General Workings Inc.’s replacement of a popular browser-based game called *Running Fred* with their own software program, called *Weekly Android Apps*, on users’ desktops, which contained code that would install, without adequate disclosure to users, apps on user’s mobile devices, without informing consumers. The complaint alleges that Respondents installed software, including Chrome browser extensions and mobile apps, onto users’ desktops and mobile devices without adequately disclosing to users that the software would be installed. The consent order requires Respondents to clearly and conspicuously disclose the types of information their products and services will access, how that information will be used, and the nature of any changes to Respondents’ products and services. The order also requires Respondents to display built-in permission notices or approvals, and to obtain consumer’s express affirmative consent prior to installation or material changes of any product or service.

Participants

For the *Commission*: Alexander E. Reicher and Jacob Snow.

For the *Respondents*: Nate Garhart, Cobalt LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that General Workings Inc., a corporation, and Ali Moiz and Murtaza Hussain, individually and as officers of the corporation (collectively “Respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges: