UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
HIKMA PHARMACEUTICALS PLC, **a corporation;**	)	
and	)	
	)	**Docket No. C-**
C.H. BOEHRINGER SOHN AG & Co. KG, **a corporation.**	)	

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 "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 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.

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 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.

VIII. VIOLATIONS CHARGED

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

2. 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 __ day of February 2016, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: