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;	)	**Docket No. C-4568**

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Hikma Pharmaceuticals PLC ("Respondent" or "Hikma"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, "Roxane") from Boehringer Ingelheim Corporation ("Boehringer") in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

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

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

II. THE PROPOSED ACQUISITION

3. Pursuant to the terms of a Stock Purchase Agreement dated July 28, 2015, as amended, among Respondent, Eurohealth (U.S.A.), Inc., and Boehringer, Respondent intends to acquire 100% of the issued and outstanding shares of Roxane for approximately $2 billion in cash and stock (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

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

a. 5 mg, 10 mg, and 20 mg generic prednisone tablets;

b. generic lithium carbonate capsules; and

c. generic flecainide tablets.

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

IV. THE STRUCTURE OF THE MARKETS

6. Generic prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. In addition to its use as an anti-inflammatory medication, prednisone is used as an immunosuppressant medication. In the United States, five firms supply 5 mg, 10 mg, and 20 mg generic prednisone tablets: Hikma; Roxane; Allergan, Inc.; Jubilant Cadista Pharmaceuticals, Inc.; and Endo International plc. The Acquisition would therefore reduce the number of suppliers of 5 mg, 10 mg, and 20 mg generic prednisone tablets from five to four.

7. Generic lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. Lithium therapy reduces the frequency of manic episodes and diminishes the intensity of episodes when they occur. There are four firms that currently supply generic lithium carbonate capsules: Hikma, Roxane, Glenmark Pharmaceuticals Ltd., and Camber Pharmaceuticals Inc. The Acquisition would therefore reduce the number of suppliers of generic lithium carbonate capsules from four to three.

8. Generic flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. Four firms currently market generic flecainide tablets: Roxane, Amneal Pharmaceuticals, ANI Pharmaceuticals, Inc. and Citron Pharma. Hikma owns the U.S. marketing rights to a generic flecainide product that has been filed with the U.S. Food and Drug Administration ("FDA"). Upon approval, Hikma likely would be the fifth supplier of generic

flecainide tablets. The Acquisition would therefore eliminate the entry of a fifth independent market participant.

V. ENTRY CONDITIONS

9. Entry into each of the relevant markets described in Paragraphs 6 through 8 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

10. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

a. by eliminating actual, direct, and substantial competition between Hikma and Roxane and reducing the number of independent significant competitors in the markets for generic 5 mg, 10 mg, and 20 mg prednisone tablets and generic lithium capsules, thereby increasing the likelihood that: (1) Hikma would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and

b. by eliminating future competition between Hikma and Roxane in the market for generic flecainide tablets, thereby (1) increasing the likelihood that the combined entity would forgo or delay the launch of the generic flecainide tablets to which Hikma owns the U.S. marketing rights; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

VII. VIOLATIONS CHARGED

1. The Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

2. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of February, 2016, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL: