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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
LUPIN LTD,	)	
a limited liability corporation;	)	
GAVIS PHARMACEUTICALS LLC,	)	
a limited liability corporation;	)	
and	)	**Docket C-4566**
NOVEL LABORATORIES, INC.,	)	
a corporation.	)	

COMPLAINT

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

I. RESPONDENTS

1. Respondent Lupin is a corporation organized, existing and doing business under and by virtue of the laws of India with its principal executive offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 200 051, India, and its United States address for service of process and the Complaint, the Decision and Order, and the

Order to Maintain Assets, as follows: Corporate Secretary, Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, MD 21202.

2. Respondent Gavis is a limited liability corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

3. Respondent Novel is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

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

II. THE PROPOSED ACQUISITIONS

5. Pursuant to Purchase and Sale Agreements dated July 23, 2015, Lupin plans to acquire (1) all of the outstanding interests of Gavis for approximately $765.6 million; and (2) all of the voting securities of Novel for approximately $83.6 million (the "Acquisitions"). Gavis and Novel are related companies: Novel specializes in the development and manufacture of generic products while Gavis markets and sells the products developed by Novel. The Acquisitions are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

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

    a. generic doxycycline monohydrate capsules; and

    b. generic mesalamine extended release ("ER") capsules.

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

IV. THE STRUCTURE OF THE MARKETS

8. Generic doxycycline monohydrate capsules are antibiotics used for treating a variety of different bacterial infections, including respiratory infections, urinary tract infections, severe acne, skin and skin structure infections, Lyme disease, and anthrax. In the United States, five companies supply generic doxycycline monohydrate capsules: Lupin, Gavis, Endo International plc, Allergan, Inc., and Sun Pharmaceutical Industries Ltd. All five companies offer the 100 mg strength, but only four companies, including Lupin and Gavis, offer the 50 mg and 75 mg strengths. Gavis is a recent entrant into the market, having just launched its product in late July 2015.

9. Generic mesalamine ER capsules are used to treat ulcerative colitis. Valeant Pharmaceuticals markets Apriso, the branded version of the product, which is available in a 375 mg formulation. No generic version of mesalamine ER capsules is currently available in the United States. Lupin and Gavis/Novel are developing generic mesalamine ER capsules and are two of a limited number of suppliers capable of entering the market in the near future.

V. ENTRY CONDITIONS

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

VI. EFFECTS OF THE ACQUISITIONS

11. The effects of the Acquisitions, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

    a. by eliminating actual, direct, and substantial competition between Lupin and Gavis/Novel and reducing the number of independent significant competitors in the market for generic doxycycline monohydrate capsules, thereby increasing the likelihood that: (1) Lupin would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and

    b. by eliminating future competition between Lupin and Gavis/Novel in the market for generic mesalamine ER capsules, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of one of the generic mesalamine ER capsule products in development; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

VII. VIOLATIONS CHARGED

12. The Acquisitions described in Paragraph 5 constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

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

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighteenth day of February, 2016 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: