

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright

In the Matter of)

ENDO HEALTH SOLUTIONS INC.,)
a corporation;)

BOCA LIFE SCIENCE HOLDINGS, LLC,)
a limited liability company;)

Docket C-4430

and)

BOCA PHARMACAL, LLC,)
a limited liability company.)

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 Endo Health Solutions Inc. (“Endo”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Boca Pharmacal, LLC, an entity subject to the jurisdiction of the Commission, from Boca Life Science Holdings, LLC (“Boca”) 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 Endo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its corporate office and principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Qualitest, a part of Endo based in Huntsville, Alabama, manufactures and markets all of Endo’s generic pharmaceutical products.

2. Respondent Boca and Respondent Boca Pharmacal, LLC are limited liability companies organized, existing, and doing business under and by virtue of the laws of the State of Florida, with their corporate offices and principal places of business located at 3550 NW 126th Avenue, Coral Springs, Florida 33065.

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. Pursuant to a Membership Purchase and Sale Agreement dated August 27, 2013 (“Agreement”), Endo proposes to acquire all of the non-corporate interests of Boca Pharmacal, LLC from its parent entity, Boca, for approximately \$225 million (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 pharmaceutical products:

- a. generic multivitamin drops containing 0.25mg fluoride (“generic PolyViFlor 0.25mg drops”);
- b. generic multivitamin drops containing 0.5mg fluoride (“generic PolyViFlor 0.5mg drops”);
- c. generic multivitamin drops with 0.25mg fluoride and iron (“generic PolyViFlor 0.25mg drops with iron”);
- d. generic multivitamin drops with 0.25mg fluoride and folate (“generic TriViFlor 0.25mg drops”);
- e. generic oral syrup containing brompheniramine maleate (2mg/5ml), dextromethorphan hydrobromide (10mg/5ml), and pseudoephedrine hydrochloride (30mg/5ml) (“generic Bromfed-DM”);
- f. generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml) (“generic Zamicet”); and
- g. generic acetic acid, glacial (2%) with hydrocortisone (1%) ear drops (“generic Vosol HC”).

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. Each of the multivitamin drops described herein ((1) generic PolyViFlor 0.25mg drops; (2) generic PolyViFlor 0.5mg drops; (3) generic PolyViFlor 0.25mg drops with iron; and (4) generic TriViFlor 0.25mg drops), are prescribed for children who do not have access to fluoridated water. The market for generic PolyViFlor 0.25mg drops is highly concentrated with only three current suppliers for the drug: Endo, Boca, and Libertas Pharma Inc. (“Libertas”). Endo has a market share of approximately 59%, Boca has a market share of approximately 36%, and Libertas has a market share of approximately 5%. Thus, the Acquisition would reduce the number of suppliers of generic PolyViFlor 0.25mg drops from three to two and the merged entity would have a market share in excess of 90%. The Acquisition would increase the Herfindahl-Hirschman Index concentration (“HHI”) by 4,248 for a post-merger total of 6,918.

8. Only Endo and Boca market generic PolyViFlor 0.5mg drops. Endo has a market share of approximately 61% and Boca has the remaining 39% share of the market. Thus, the Acquisition would create a monopoly in the generic PolyViFlor 0.5mg drops market and would increase the HHI by 4,758 to a total of 10,000.

9. The market for generic PolyViFlor 0.25mg drops with iron is highly concentrated with only three current suppliers: Endo, Boca, and Libertas. Endo has a market share of approximately 56%, Boca has a market share of approximately 38%, and Libertas has a market share of approximately 6%. Thus, the Acquisition would substantially increase concentration in the market by consolidating the number of suppliers of generic PolyViFlor 0.25mg drops with iron from three to two and the merged entity would have a market share in excess of 90%. The Acquisition would increase the HHI concentration by 4,256 for a post-merger total of 8,872.

10. The market for generic TriViFlor 0.25mg drops has four suppliers: Endo, Boca, Libertas, and Sancilio & Company, Inc. (“Sancilio”). Endo has a market share of approximately 51%, Boca has a market share of approximately 22%, Libertas has a market share of approximately 26%, and Sancilio has a market share of approximately 1%. Thus, the Acquisition would substantially increase concentration in the market by consolidating the number of suppliers of generic TriViFlor 0.25mg drops from four to three. The Acquisition would increase the HHI concentration by 2,244 for a post-merger total of 6,006.

11. Generic Bromfed-DM is a product used for the treatment of symptoms caused by the common cold, flu, hay fever, sinusitis, bronchitis, and other respiratory illnesses. No company currently markets a generic version of Bromfed-DM in the United States. Endo and Boca are among a limited number of firms that have generic Bromfed-DM products in

development. Therefore, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Bromfed-DM.

12. Generic Zamicet is prescribed for the relief of moderate to moderately severe pain. No company currently markets generic Zamicet in the United States. Endo and Boca are among a limited number of firms that have generic Zamicet products in development. Thus, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Zamicet.

13. Generic Vosol HC is a product used to treat Swimmer's Ear. The market for generic Vosol HC has three suppliers: Actavis plc ("Actavis"), the Taro Pharmaceuticals Industries Ltd. unit of Sun Pharma Industries ("Sun"), and Endo. Boca is one of a limited number of firms that has a generic Vosol HC product in development. Therefore, the Acquisition would be likely to substantially increase concentration in the market by reducing the number of likely future suppliers of generic Vosol HC.

VI. ENTRY CONDITIONS

14. 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 be lengthy. Entry into the markets for generic PolyViFlor 0.25mg drops, generic PolyViFlor 0.5mg drops, generic PolyViFlor 0.25mg drops with iron, and generic TriViFlor 0.25mg drops is particularly unlikely because new firms, unlike existing manufacturers whose facilities pre-date the FDA's current regulatory approval process, would be required to invest in filing Abbreviated New Drug Applications ("ANDAs") and wait for approvals for relatively small market opportunities. In addition, no other entry by firms for which the FDA approval process is already underway would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

15. The effects of the Acquisition, if consummated, may be to substantially lessen competition and 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 Endo and Boca and reducing the number of competitors in the markets for (1) generic PolyViFlor 0.25mg drops; (2) generic PolyViFlor 0.5mg drops; (3) generic PolyViFlor 0.25mg drops with iron; and (4) generic TriViFlor 0.25mg drops, thereby: (a) increasing the likelihood that Endo will be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices; and

- b. by eliminating future competition between Endo and Boca and reducing the number of generic competitors in the markets for (1) generic oral syrup containing brompheniramine maleate (2mg/5ml), dextromethorphan hydrobromide (10mg/5ml), and pseudoephedrine hydrochloride (30mg/5ml); (2) generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml); and (3) generic acetic acid, glacial (2%) with hydrocortisone (1%) ear drops, 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.

VIII. VIOLATIONS CHARGED

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

17. 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-ninth day of January 2014, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: