

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT**

*In the Matter of Endo Health Solutions Inc., Boca Life Science Holdings, LLC, and Boca
Pharmacal, LLC
File No. 131-0225*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Endo Health Solutions Inc. (“Endo”) that is designed to remedy the anticompetitive effects in seven generic pharmaceutical markets resulting from Endo’s acquisition of the non-corporate interests of Boca Pharmacal, LLC from Boca Life Science Holdings, LLC (“Boca”). Under the terms of the proposed Consent Agreement, Boca is required to relinquish all rights and assets related to Boca’s four prescription fluoride multivitamin drops: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; and (4) generic TriViFlor 0.25mg multivitamin drops to Sonar Products, Inc. (“Sonar”), the current manufacturer of all four multivitamin drops products. Furthermore, the parties are required to divest to Rhodes Pharmaceuticals, Inc. (“Rhodes”) all of Endo’s rights and interests relating to: (1) generic oral syrup containing brompheniramine maleate (2mg/5ml), dextromethorphan hydrobromide (10mg/5ml), and pseudoephedrine hydrochloride (30mg/5ml) (“generic Bromfed-DM”); (2) generic oral solution containing hydrocodone (10mg/15ml) and acetaminophen (325mg/15ml) (“generic Zamicet”); as well as Boca’s rights and interests relating to generic glacial acetic acid (2%) with hydrocortisone (1%) otic drops (“generic Vosol HC”).

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 Purchase and Sale Agreement dated August 27, 2013, Endo proposes to acquire the non-corporate interests of Boca Pharmacal, LLC from Boca, for approximately \$225 million (the “Proposed Acquisition”). 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 current and future competition in U.S. markets for the following generic pharmaceutical products: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; (4) generic TriViFlor 0.25mg multivitamin drops; (5) generic Bromfed-DM; (6) generic Zamicet; and (7) generic Vosol HC (collectively, the “Products”). The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of suppliers in the relevant markets, each of which has or will have a limited number of market participants. In pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market would have a direct and substantial anticompetitive effect on pricing.

The Proposed Acquisition would reduce current competition in four generic prescription multivitamin markets: (1) generic PolyViFlor 0.25mg multivitamin drops; (2) generic PolyViFlor 0.5mg multivitamin drops; (3) generic PolyViFlor 0.25mg multivitamin drops with iron; and (4) generic TriViFlor 0.25mg multivitamin drops. Each of these generic multivitamin drops products contains fluoride and is prescribed for children who do not have access to fluoridated water. The structure of these markets is as follows:

- The generic PolyViFlor 0.25mg multivitamin drops market currently has three suppliers: Endo, with a market share of approximately 59%, Boca, with a market share of approximately 36%, and Libertas Pharma Inc. (“Libertas”), with a market share of approximately 5%. The proposed transaction would reduce the number of suppliers in this market from three to two, and would give the merged firm a market share in excess of 90%.
- Endo and Boca are the only two firms that market generic PolyViFlor 0.5mg multivitamin drops. Endo has a market share of approximately 61% and Boca has a market share of approximately 39%. Thus, the proposed transaction would create a monopoly in the generic PolyViFlor 0.5mg multivitamin drops market.
- The generic PolyViFlor 0.25mg multivitamin drops with iron market currently has three suppliers: Endo, with a market share of approximately 56%, Boca, with a market share of approximately 38%, and Libertas, with a market share of approximately 6%. The proposed transaction would reduce the number of suppliers in this market from three to two, and would give the merged firm a market share in excess of 90%.
- The generic TriViFlor 0.25mg multivitamin drops market has four participants: Endo, with a market share of approximately 51%, Libertas, with a market share of approximately 26%, Boca, with a market share of approximately 22%, and Sancilio & Company, Inc. (“Sancilio”) with a market share of approximately 1%. The proposed transaction would reduce the number of suppliers of generic TriViFlor 0.25mg multivitamin drops from four to three, and would give the merged firm a market share in excess of 70%.

In addition to reducing current competition in the four generic prescription multivitamin markets, the proposed transaction would significantly reduce future competition in the generic Vosol HC market. Generic Vosol HC ear drops are prescribed for the treatment of Swimmer's Ear. Three firms currently supply generic Vosol HC: Actavis plc ("Actavis"), Sun Pharma Industries ("Sun"), and Endo. Actavis has a market share of approximately 79% and Sun has a market share of approximately 21%. Although Endo's recent market share has been minimal because it withdrew its product last year, its market share was 32% as recently as two years ago. Endo owns the Abbreviated New Drug Application for generic Vosol HC and could relaunch its product at any time. Boca appears poised to be the next entrant with a generic Vosol HC product. Endo's acquisition of Boca would therefore deprive consumers of the increased competition and likely price reductions that would have occurred as a result of Boca's entry.

The transaction will also reduce future competition in two generic markets that do not yet exist, but will be highly concentrated at the time Endo and Boca enter: the generic Bromfed-DM market and the generic Zamicet market. When generic entry occurs, Endo and Boca would likely be among a limited number of suppliers in both markets. Thus, the proposed transaction would significantly reduce the number of likely future suppliers of these products to the detriment of consumers.

- Generic Bromfed-DM is prescribed for the treatment of symptoms caused by the common cold, flu, sinusitis, and other respiratory illnesses. Currently, there are no generic versions of Bromfed-DM available in the United States. Endo and Boca are two of a limited number of likely potential suppliers of generic Bromfed-DM. The Proposed Acquisition would eliminate a likely entrant into what will be a concentrated market for generic Bromfed-DM.
- Generic Zamicet is prescribed for the relief of moderate to moderately severe pain. Currently, there are no generic versions of Zamicet available in the United States. Endo and Boca are two of a limited number of likely potential suppliers of generic Zamicet. The Proposed Acquisition would eliminate a likely entrant into what will be a concentrated market for generic Zamicet.

Entry

Entry into the markets for the Products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including U.S. Food and Drug Administration ("FDA") approval, is costly and lengthy. Entry into the four multivitamins with fluoride markets is particularly unlikely because new firms, unlike existing manufacturers whose products pre-date the FDA's current regulatory approval process, would be required to file Abbreviated New Drug Applications ("ANDAs") and wait for approvals for relatively small market opportunities.

Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing markets or in future generic markets.

In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them.

The evidence shows that anticompetitive effects are likely to result from the proposed transaction, due to a decrease in the number of independent competitors in the markets at issue. In each of the current prescription fluoride multivitamin drops markets, industry participants have indicated that the presence of Boca as a competitor has allowed them to negotiate lower prices from other suppliers, including Endo.

The evidence also shows that the Proposed Acquisition would eliminate significant future competition between Endo and Boca. Although neither Endo nor Boca currently has a marketed product in the generic Vosol HC market, and no generic product has yet gained approval in either the generic Zamiket or generic Bromfed-DM markets, the Proposed Acquisition eliminates one likely future entrant from a very limited pool of future entrants in each of these markets.

By eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs, absent a remedy.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each of the relevant product markets. Pursuant to the Consent Agreement, Boca is required to return to Sonar all of Boca's rights related to the four prescription fluoride multivitamin drops. Sonar owns and manufactures these products and, prior to the Proposed Acquisition, had an exclusive marketing and distribution agreement with Boca for these products. Under the proposed Asset Maintenance Order, Boca is required to continue to distribute the multivitamin drops for Sonar for a period of up to six months in order to allow Sonar time to establish itself with a new marketing and distribution partner. Sonar will choose another marketing and distribution partner from among several interested parties, thereby replicating the competition in the relevant markets posed by pre-acquisition Boca.

Further, Endo is required to divest to Rhodes all of its rights and interests in generic Bromfed-DM and generic Zamiket as well as all of Boca's rights and interests in generic Vosol

HC. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the acquisition.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Rhodes is not an acceptable acquirer of the divested assets, or that the manner of the divestitures is not acceptable, the parties must unwind the sale of rights to Rhodes 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 Order requires Endo and Boca to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Endo and Boca must transfer their respective manufacturing technologies for the Products to Rhodes and must supply Rhodes with these products during a transitional period.

The Commission has agreed to appoint a representative of Quantic Regulatory Services, LLC to act as an interim monitor to assure that Endo and Boca expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement. In order to ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Endo and Boca to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent 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.