ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Akorn Enterprises, Inc. and Hi-Tech Pharmacal Co., Inc.
File No. 131-0221, Docket No. C-4452

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Akorn Enterprises, Inc. ("Akorn") that is designed to remedy the anticompetitive effects in five generic pharmaceutical markets resulting from Akorn's acquisition of Hi-Tech Pharmacal Co., Inc. ("Hi-Tech"). Under the terms of the proposed Consent Agreement, the parties are required to divest either Akorn's or Hi-Tech's rights and assets related to three generic ophthalmic prescription products: (1) generic Ciloxan drops, (2) generic Ilotycin ointment, and (3) generic Quixin drops, and two topical anesthetic products, (4) generic Xylocaine jelly, and (5) EMLA cream (collectively, the "Products") to Watson Laboratories, Inc. ("Watson"), a wholly-owned subsidiary of Actavis plc.

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 an Agreement and Plan of Merger dated August 26, 2013, Akorn proposes to acquire all of the voting securities of Hi-Tech, for approximately $640 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/or future competition in U.S. markets for the following pharmaceutical products: (1) generic Ciloxan drops, (2) generic Ilotycin ointment, (3) generic Quixin drops, (4) generic Xylocaine jelly, and (5) generic EMLA cream. 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 markets for two generic prescription ophthalmic products--generic Ciloxan drops and generic Quixin drops--as well as reduce current competition in the markets for generic Xylocaine jelly and generic EMLA cream, which are topical anesthetic prescription products. The structure of these markets is as follows:

- The generic Ciloxan opthalmic drops market currently has four suppliers: Akorn, with a market share of approximately 12%, Hi-Tech, with a market share of approximately 16%, Novartis Corporation ("Novartis"), with a market share of approximately 47%, and PACK Pharmaceuticals ("PACK"), with a market share of approximately 25%. The proposed transaction would reduce the number of suppliers in this market from four to three, and would give the merged firm a market share of approximately 28%.

- The generic Quixin ophthalmic drops market currently has three suppliers: Akorn, with a market share of approximately 15%, Hi-Tech, with a market share of approximately 23%, and PACK, with a market share of approximately 62%. 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 of approximately 38%.

- The generic Xylocaine jelly market has three suppliers: Akorn, with a market share of approximately 39%, Hi-Tech, with a market share of approximately 14%, and Amphastar Pharmaceuticals, Inc. ("Amphastar"), with a market share of approximately 47%. The proposed transaction would reduce the number of suppliers of generic Xylocaine from three to two, and would give the merged firm a market share in excess of 50%.

- The generic EMLA cream market currently has four suppliers: Akorn, with a market share of approximately 12%, Hi-Tech, with a market share of approximately 62%, Novartis, with a market share of approximately 22%, and Global Pharmaceuticals ("Global") with a market share of approximately 3%. In addition to marketing generic EMLA, Akorn markets the branded product. The proposed transaction would reduce the number of suppliers in the generic market from four to three, and would give the merged firm a market share in excess of 70%.

The proposed transaction would also reduce future competition in the generic Ilotycin ophthalmic ointment market. Generic Ilotycin ophthalmic ointment is prescribed for the treatment of bacterial infections in the eye. Three firms currently supply generic Ilotycin: Akorn, Perrigo Company ("Perrigo"), and Bausch + Lomb, Inc. ("Bausch + Lomb"). Bausch + Lomb leads the market with a 57% share with Akorn and Perrigo having market shares of 31% and 12%, respectively. Hi-Tech appears poised to be the next entrant with a generic Ilotycin product and there are no other likely entrants for the foreseeable future. Akorn's acquisition of Hi-Tech would therefore deprive consumers of the increased competition and likely price reductions that would have occurred as a result of Hi-Tech's entry.

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. Industry participants also note that expertise and facilities associated with manufacturing topical products, including sterile products such as ophthalmic products is sufficiently specialized that a relatively small number of firms participate in such markets.

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 generic prescription markets, industry participants have indicated that the presence of Hi-Tech as a competitor has allowed them to negotiate lower prices from other suppliers, including Akorn, and has allowed them to locate additional supply in times of product shortages from their existing suppliers.

The evidence also shows that the Proposed Acquisition would eliminate significant future competition between Akorn and Hi-Tech. Although Hi-Tech does not currently have a marketed product in the generic Ilotycin market, the Proposed Acquisition eliminates the next most likely entrant from a very limited pool of future entrants.

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, the parties are required to divest Akorn's or Hi-Tech's rights and assets related to the Products to Watson. Further, the proposed Consent Agreement requires Akorn to assign its contract manufacturing agreement for branded and generic EMLA to Watson. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

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 Watson 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 Watson 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 Akorn and Hi-Tech 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. Depending on the product, Akorn or Hi-Tech must transfer their respective manufacturing technologies for the Products to Watson and must supply Watson with these products during a transitional period.

The Commission has agreed to appoint Denise Smart from Smart Consulting Group, LLC to act as an interim monitor to assure that Akorn and Hi-Tech 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 Akorn and Hi-Tech 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.