

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

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

	)	
<b>In the Matter of</b>	)	
	)	
<b>AKORN, INC.,</b>	)	
a corporation;	)	
	)	<b>Docket No. C-4452</b>
<b>and</b>	)	
	)	
<b>HI-TECH PHARMACAL CO., INC,</b>	)	
a corporation.	)	
	)	

**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 Respondent Akorn, Inc. (“Akorn”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Hi-Tech Pharmacal Co., Inc. (“Hi-Tech”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, 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 Akorn is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its corporate head office and principal place of business located at 1925 W. Field Court, Suite 300, Lake Forest, Illinois, 60045.

2. Respondent Hi-Tech is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 369 Bayview Avenue, Amityville, New York, 11701.

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 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 ACQUISITION**

4. Pursuant to an Agreement and Plan of Merger dated August 26, 2013, Akorn proposes to acquire Hi-Tech for approximately \$640 million (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

## **III. THE RELEVANT 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 pharmaceutical products:

- a. generic ophthalmic drops containing 0.3% ciprofloxacin hydrochloride (“generic Ciloxan drops”);
- b. generic ophthalmic ointment containing 0.5% erythromycin (“generic Ilotycin ointment”);
- c. generic ophthalmic drops containing 0.5% levofloxacin (“generic Quixin drops”);
- d. generic topical jelly containing 2% lidocaine (“generic Xylocaine jelly”);
- e. generic topical cream containing 2.5% lidocaine with prilocaine (“generic EMLA cream”);

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

## **IV. THE STRUCTURE OF THE MARKETS**

7. Generic Ciloxan drops are an antibiotic used to treat bacterial infections of the eye and corneal ulcers. The market for generic Ciloxan drops is highly concentrated with only four current suppliers—Akorn, Hi-Tech, Novartis Corp. (“Novartis”), and Nexus Pharmaceuticals, Inc. (“Nexus”), which distributes its product through PACK Pharmaceuticals (“PACK”). The Acquisition would reduce the number of suppliers of generic Ciloxan drops from four to three,

would increase the Herfindahl-Hirschman Index concentration (“HHI”) by 384, from 3234 to a post-merger total of 3618, and would create a merged entity having a market share in excess of 28%.

8. Generic Ilotycin ointment is an antibiotic used to treat and prevent bacterial eye infections. Three firms—Akorn, Bausch & Lomb, Inc. (“Bausch & Lomb”), and Perrigo Company plc (“Perrigo”)—currently supply generic Ilotycin ointment in this highly concentrated market, which has an HHI in excess of 4000. Hi-Tech is likely to be the next entrant into this market as it is the only firm expected to file an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) in the foreseeable future. Thus, the Acquisition would reduce the number of suppliers of generic Ilotycin ointment from four to three.

9. Generic Quixin drops are an antibiotic used to treat bacterial eye infections. The market for generic Quixin drops is highly concentrated with only three current suppliers—Akorn, Hi-Tech, and Nexus, which distributes its product through PACK. Akorn has a market share of approximately 15% and Hi-Tech has a market share of approximately 23%. The Acquisition would reduce the number of suppliers of generic Quixin drops from three to two, would increase the HHI by 690, from 4598 to a post-merger total of 5288, and would create a merged entity having a market share in excess of 38%.

10. Generic Xylocaine jelly is a topical jelly used to treat and prevent pain in procedures involving male and female urethra, to treat painful urethritis topically, and also as an anesthetic lubricant for endotracheal intubation. Three firms currently supply generic Xylocaine jelly in this highly concentrated market—Akorn, Hi-Tech, and Amphastar Pharmaceuticals, Inc. (“Amphastar”). Akorn has a market share of approximately 39% and Hi-Tech has a market share of approximately 14%. The Acquisition would reduce the number of suppliers of generic Xylocaine jelly from three to two, would increase the HHI by 1092, from 3926 to a post-merger total of 5018, and would create a merged entity having a market share in excess of 53%.

11. Generic EMLA cream is a topical anesthetic for use on normal, intact skin for local analgesia and on genital mucous membranes for superficial minor surgery or as a pretreatment for infiltration anesthesia. The market for generic EMLA cream is highly concentrated with only four current suppliers—Akorn, Hi-Tech, Novartis, and TOLMAR, Inc. (“TOLMAR”), which distributes its product through Impax Laboratories, Inc. (“Impax”). Akorn has a market share of approximately 12% and Hi-Tech has a market share of approximately 62%. The Acquisition would reduce the number of suppliers of generic EMLA cream from four to three, would increase the HHI by 1488, from 4481 to a post-merger total of 5969, and would create a merged entity having a market share in excess of 74%.

## **V. ENTRY CONDITIONS**

12. 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. 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**

13. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to 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 Akorn and Hi-Tech and reducing the number of significant competitors in the markets for (1) generic Ciloxan drops; (2) generic Quixin drops; (3) generic Xylocaine jelly; and (4) generic EMLA cream, thereby increasing the likelihood that: (a) Akorn would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Akorn and Hi-Tech and reducing the number of generic competitors in the market for generic Ilotycin ointment, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of this product 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 this product.

## **VII. VIOLATIONS CHARGED**

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

15. 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 eleventh day of April, 2014 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL: