**1510011**

**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**

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

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| **In the Matter of** | ) | |
| **IMPAX LABORATORIES, INC.,** **a corporation;** | ) | |
| **ROUNDTABLE HEALTHCARE PARTNERS II, L.P.** **a limited partnership;** | ) | **Docket No. C-4511** |
| **and** | ) | |
| **TOWER HOLDINGS, 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 Impax Laboratories, Inc. ("Impax"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent Tower Holdings, Inc. ("Tower") and Lineage Therapeutics Inc. ("Lineage"), subsidiaries of Respondent RoundTable Healthcare Partners II, L.P. ("RoundTable"), all of which are corporations or partnerships 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 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 Impax is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at 30831 Huntwood Avenue, Hayward, California 94544.

2. Respondent RoundTable is a limited partnership organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at 272 E. Deerpath Road, Suite #350, Lake Forest, Illinois 60045. Lineage, a subsidiary of Respondent RoundTable, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at 2 Walnut Grove Drive, Suite 190, Horsham, Pennsylvania 19044.

3. Respondent Tower is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at 215 Wood Avenue, Middlesex, New Jersey 08846. CorePharma, L.L.C. ("CorePharma"), a subsidiary of Respondent Tower, is a corporation organized, existing, and doing business under and by virtue of the laws of the States of Delaware with its headquarters located at 215 Wood Avenue, Middlesex, New Jersey 08846.

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 ACQUISITION

5. Pursuant to a Stock Purchase Agreement executed October 8, 2014, by and among Tower, Lineage, RoundTable and Impax, Impax proposes to acquire 100% of the outstanding voting securities of Tower and Lineage from RoundTable in a transaction valued at approximately $700 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

6. 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 5 mg pilocarpine hydrochloride tablets; and

b. generic ursodiol tablets.

7. 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 the relevant lines of commerce.

## IV. THE STRUCTURE OF THE MARKETS

8. Generic pilocarpine is used to treat dry mouth. The market for generic 5 mg pilocarpine hydrochloride tablets is highly concentrated with only two current suppliers—Lannett Company, Inc. and Actavis plc. ("Actavis"). While neither Impax nor CorePharma is currently marketing the product, each holds an approved Abbreviated New Drug Application ("ANDA") to market generic 5 mg pilocarpine hydrochloride tablets in the United States. Both companies are well positioned to enter the generic 5 mg pilocarpine hydrochloride market, sell the product, and are expected to enter the market in the near future. No other suppliers are expected to enter this market in time to prevent the competitive harm likely to result from the Acquisition.

9. Generic ursodiol tablets are used to treat primary biliary cirrhosis of the liver. Four firms—Impax, Actavis, Par Pharmaceutical Companies, Inc. and Glenmark Pharmaceuticals Limited—currently supply generic ursodiol tablets in this concentrated market. This market has recently experienced supply shortages that have created an imbalance between supply and demand. CorePharma is developing generic ursodiol, is one of a limited number of firms with an ANDA under review by the U.S. Food and Drug Administration ("FDA"), and is the next likely entrant to enter the market within the near future No suppliers, other than CorePharma, are expected to enter this market in time to prevent the competitive harm likely to result from the Acquisition. Thus, the Acquisition would likely reduce the number of future suppliers of generic ursodiol tablets from five to four.

## 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 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

11. The effects of the Acquisition, 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 future competition between Impax and CorePharma in the market for generic 5 mg pilocarpine hydrochloride tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of either Impax's or CorePharma's product; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from both Impax and CorePharma supplying this product.

b. By eliminating future competition between Impax and CorePharma in the market for generic ursodiol, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of CorePharma's products; 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 this product.

## VII. VIOLATIONS CHARGED

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

13. The Acquisition 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 fifth day of March, 2015, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: