

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Maureen K. Ohlhausen, Acting Chairman
Terrell McSweeney

In the Matter of)
)
)
 AMNEAL HOLDINGS, LLC,)
 a limited liability company;)
)
 AMNEAL PHARMACEUTICALS LLC,)
 a limited liability company;)
) **Docket No. C-4650**
 IMPAX LABORATORIES, INC.,)
 a corporation;)
)
 and)
)
 IMPAX LABORATORIES, LLC,)
 a limited liability company.)

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 Amneal Holdings, LLC, and Respondent Amneal Pharmaceuticals LLC (collectively, “Amneal”), corporations subject to the jurisdiction of the Commission, have agreed to acquire the equity interests of Respondent Impax Laboratories, Inc., and Respondent Impax Laboratories, LLC (collectively, “Impax”), corporations 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 Amneal Holdings, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Respondent Amneal Pharmaceuticals LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.
2. Respondent Impax Laboratories, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 30831 Huntwood Avenue, Hayward, California 94544. Respondent Impax Laboratories, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 30831 Huntwood Avenue, Hayward, California 94544.
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 engages in business that 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 business combination agreement dated October 17, 2017, Respondent Amneal proposes to acquire the equity interests of Respondent Impax in a series of transactions valued at approximately \$1.45 billion (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. 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. desipramine hydrochloride tablets;
 - b. ezetimibe and simvastatin immediate release (“IR”) tablets;
 - c. felbamate tablets;

- d. aspirin and dipyridamole extended release (“ER”) capsules;
 - e. azelastine nasal spray;
 - f. diclofenac sodium and misoprostol delayed release (“DR”) tablets;
 - g. erythromycin tablets;
 - h. fluocinonide-E cream;
 - i. methylphenidate hydrochloride ER tablets; and
 - j. olopatadine hydrochloride nasal spray.
6. 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

7. Desipramine hydrochloride is a tricyclic antidepressant. Only five companies currently sell generic desipramine hydrochloride tablets in the United States: Amneal, Impax, Heritage Pharmaceuticals, Inc. (“Heritage”), Sandoz, and Teva Pharmaceutical Industries Ltd. (“Teva”). Sales by Teva, Sandoz, and Amneal account for more than 95 percent of the market. Heritage accounts for the remaining 5 percent while Impax only launched its product in late 2017. The Acquisition would reduce the number of suppliers of generic desipramine hydrochloride tablets from five to four and eliminate the most recent entrant into the market.
8. Ezetimibe and simvastatin is used to improve cholesterol and lower triglycerides. Only four companies currently sell generic ezetimibe and simvastatin IR tablets in the United States: Amneal, Impax, Dr. Reddy’s Laboratories (“Dr. Reddy’s”), and Teva. Sales by Impax account for more than half the market, while Dr. Reddy’s and Teva share the remainder. Amneal entered the generic ezetimibe and simvastatin IR tablets market at the end of 2017. The Acquisition would reduce the number of suppliers from four to three and eliminate the most recent entrant.
9. Felbamate is an anticonvulsant used in the treatment of epilepsy. Only four companies currently sell generic felbamate tablets in the United States: Amneal, Impax, Alvogen, and Wallace Pharmaceuticals, Inc. (“Wallace”). The Acquisition would reduce the number of suppliers of generic felbamate from four to three.

10. Aspirin and dipyridamole is an antiplatelet therapy used to reduce the risk of stroke. Only Amneal currently sells generic aspirin and dipyridamole ER capsules in the United States. Impax is one of only a limited number of suppliers capable of entering the market for generic aspirin and dipyridamole ER capsules in the near future.
11. Azelastine nasal spray is used to treat seasonal allergies. Three companies currently sell generic azelastine nasal spray: Impax, partnered with Perrigo Company plc (“Perrigo”); Wallace; and Apotex Inc. (“Apotex”). Amneal is one of a limited number of suppliers capable of entering the market in the near future.
12. Diclofenac sodium and misoprostol is used to provide pain relief while minimizing gastrointestinal side effects. Four companies—Amneal, Teva, Sandoz, and Exela Pharma Sciences LLC (“Exela”)—have approved ANDAs to sell generic diclofenac sodium and misoprostol DR tablets in the United States. In addition, Greenstone LLC, a Pfizer subsidiary, sells an authorized generic version. Sandoz does not sell its product directly to customers and supplies only to a private labeler. The Exela product, marketed by both Eagle Pharmaceuticals, Inc. and Dash Pharmaceuticals LLC, has limited sales. Impax, partnered with Micro Labs Limited, is one of only a few suppliers capable of entering the market for generic diclofenac sodium and misoprostol DR tablets in the near future.
13. Erythromycin is an antibiotic which until recently had only one supplier, Arbor Pharmaceuticals, LLC, in the United States. Amneal’s ANDA to sell generic erythromycin tablets was approved in March of 2018, and it has launched the product. Impax is one of a limited number of suppliers capable of entering the market for generic erythromycin in the near future.
14. Fluocinonide-E cream is a corticosteroid used on the skin to reduce swelling, redness, itching, and allergic reactions. Only four companies currently sell generic fluocinonide-E cream in the United States: Impax, Alvogen, Sun Pharmaceutical Industries Ltd. (“Sun”), and Teva. Sun and Teva are the market leaders, while Impax and Alvogen are recent entrants into the market. Amneal is one of only a few suppliers capable of entering the market for generic fluocinonide-E cream in the near future.
15. Methylphenidate hydrochloride is a central nervous system stimulant used to treat attention-deficit disorder and attention-deficit/hyperactivity disorder. Only four companies currently sell generic methylphenidate hydrochloride ER tablets in the United States: Teva is the leading supplier with more than 80 percent share, while Mylan N.V. and Trigen each have less than 10 percent share. Amneal’s ANDA was approved in February of 2018, and it has since launched the product. Impax is one of a limited number of suppliers capable of entering the market for generic methylphenidate hydrochloride ER tablets in the near future.

16. Olopatadine hydrochloride nasal spray is used to treat seasonal allergies. Three companies currently sell generic olopatadine hydrochloride nasal spray in the United States: Impax, partnered with Perrigo; Sandoz; and Apotex. Amneal is one of only a few suppliers capable of entering the market for generic olopatadine hydrochloride nasal spray in the near future.

V. ENTRY CONDITIONS

17. Entry into the relevant markets described in Paragraphs 7-16 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

18. 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 actual, direct, and substantial competition between Amneal and Impax and reducing the number of independent significant competitors in the markets for (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets, thereby increasing the likelihood that: (a) Amneal 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 Amneal and Impax in the markets for (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic

methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of each 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 each product.

VII. VIOLATIONS CHARGED

19. The Acquisition described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
20. 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-seventh day of April, 2018, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: