

2. Respondent Novitium Pharma 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 70 Lake Drive, East Windsor, New Jersey 08520.
3. Respondent Esjay 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 16732 Strasbourg Lane, Delray Beach, Florida 33446.
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 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

5. Pursuant to an agreement and plan of merger dated March 8, 2021, Respondent ANI proposes to acquire the non-corporate equity interests of Respondent Novitium in transaction valued at approximately \$210 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. 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. sulfamethoxazole-trimethoprim (“SMX-TMP”) oral suspension; and
 - b. dexamethasone tablets.
7. 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 SMX-TMP oral suspension is an antibiotic product used to treat a variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX-TMP oral suspension in the near future.

9. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Recently, dexamethasone tablets have been used to reduce mortality in hospitalized COVID-19 patients who require supplemental oxygen. Dexamethasone tablets are available in a variety of strengths, although the most widely-used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies entering the market in the near future.

V. ENTRY CONDITIONS

10. Entry into the relevant markets described in Paragraphs 6-7 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. THE 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, by eliminating future competition between ANI and Novitium in the markets for (1) generic SMX-TMP oral suspension and (2) generic dexamethasone tablets, 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

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 ninth day of November 2021 issues its Complaint against said Respondents.

By the Commission.

April J. Tabor
Secretary

SEAL: