

## ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

### *In the Matter of ANI Pharmaceuticals, Inc.; Novitium Pharma LLC; and Esjay LLC File No. 211-0101; Docket No. C-4754*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from ANI Pharmaceuticals, Inc. (“ANI”) and Novitium Pharma LLC and Esjay LLC (collectively, “Novitium”) that is designed to remedy the anticompetitive effects resulting from ANI’s acquisition of the non-corporate interests of Novitium. Pursuant to an agreement dated March 8, 2021, ANI proposes to acquire Novitium in a transaction valued at approximately \$210 million. 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 future competition in the following two U.S. markets: (1) generic SMX-TMP oral suspension; and (2) generic dexamethasone tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (“Order”), Respondents are required to divest all of ANI’s rights and assets related to the following two products to Prasco LLC (“Prasco”): (1) generic sulfamethoxazole-trimethoprim (“SMX-TMP”) oral suspension; and (2) generic dexamethasone tablets. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Prasco. The Commission also issued the Order to Maintain Assets.

The 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 Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the Consent Agreement, modify it, or make final the proposed Order.

#### **I. The Respondents**

Respondent ANI is a public specialty pharmaceutical company headquartered in Baudette, Minnesota selling both branded and generic pharmaceutical products.

Respondent Novitium is a privately-held company based in East Windsor, New Jersey. The company develops, manufactures, and commercializes generic pharmaceutical products.

#### **II. The Products and Structure of the Markets**

In human pharmaceutical markets, price(s) generally decreases as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the SMX-TMP oral suspension market, where ANI is a current competitor and Novitium is likely to enter the market. 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.

Similarly, the Proposed Acquisition would reduce future competition in the 4 mg strength of generic dexamethasone tablets market, where both ANI and Novitium are likely to enter the market in the near future. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. 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 likely to enter the market in the near future.

### **III. Entry**

Entry into the two markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

### **IV. Competitive Effects**

The Proposed Acquisition likely would delay or reduce the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the two markets at issue. While five companies, including ANI, currently market the generic SMX-TMP product in the United States, at least one has had difficulty manufacturing the product, and Novitium is one of a limited number of suppliers capable of entering the market in the near future. In the generic dexamethasone tablets market, only two companies sell the 4 mg strength in the United States today and ANI and Novitium are two of a limited number of companies entering the market in the near future. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

### **V. The Proposed Order and the Order To Maintain Assets**

The proposed Order and the Order to Maintain Assets effectively remedy the competitive concerns raised by the Proposed Combination for the two generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest ANI's rights and assets related to the two products to Prasco. The parties must accomplish these divestitures no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

While ANI and Novitium do not compete against each other in the market for generic erythromycin and ethylsuccinate granules for oral suspension, Novitium has an unexecuted

option to acquire a product from another company and ANI sells a product today. The proposed Order requires prior Commission approval before ANI or Novitium may acquire any rights or interests in certain products containing, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate. This provision allows the Commission to evaluate whether a future acquisition of the erythromycin and ethylsuccinate product would reduce competition at the time the acquisition is proposed. The proposed Order also requires ANI and Novitium to seek Commission approval before acquiring any other SMX-TMP or dexamethasone tablet product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. ANI will supply Prasco with SMX-TMP oral suspension and dexamethasone tablets for up to three years while the company transfers the manufacturing technology to Prasco's contract manufacturing designee. The proposed Order also requires ANI to provide transitional services to Prasco to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to have the products manufactured in substantially the same manner and quality employed or achieved by ANI. It also includes advice and training from knowledgeable employees of the parties. Further, the proposed Order requires prior Commission approval before Prasco may sell, license, or otherwise convey any of the assets divested pursuant to the proposed Order.

Under the proposed Order, the Commission also will appoint a Monitor to ensure that ANI and Novitium comply with their obligations under the proposed Order and Order to Maintain Assets. The Commission has appointed Denise Smart of Smart Consulting Group, LLC as the Monitor. Ms. Smart is an expert in areas such as pharmaceutical R&D, regulatory approval, manufacturing and supply, and marketing, and she has over thirty years of experience in the pharmaceutical area and has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and other government agencies, including the FDA, Department of Defense, and Health and Human Services.

The proposed Order also contains a prior approval provision relating to Prasco, which prohibits Prasco from selling the acquired products for a combined period of ten years after the Order is issued, except to an acquirer that receives the prior approval of the Commission.

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The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.