

manufactures and markets branded, generic and over-the-counter (“OTC”) pharmaceutical products, with an emphasis on dermatologic and neurologic therapeutic areas. Respondent employs approximately 3700 employees worldwide and had worldwide 2010 revenues of \$1.1 billion, the majority of which derived from U.S. sales.

2. 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

3. Pursuant to an Asset Purchase Agreement (“the Acquisition Agreement”) dated July 8, 2011, Respondent proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”).

III. THE RELEVANT MARKETS

4. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. BenzaClin; and
- b. Topical fluorouracil cream (“topical 5FU”).

5. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

6. Sanofi’s Dermik unit manufactures and markets BenzaClin, a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. Respondent owns the only Abbreviated New Drug Application (“ANDA”) for the generic version of BenzaClin, which it licenses to Mylan, Inc. (“Mylan”). Pursuant to this licensing agreement, Mylan sells the only generic of BenzaClin and Respondent receives royalties from those sales. Currently Dermik’s BenzaClin sales account for approximately 50 per cent of unit sales in the BenzaClin market, while Mylan’s generic version accounts for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

7. Topical 5FU products are used to treat actinic keratosis, a pre-cancerous lesion that can result from years of repeated sun exposure. There are three branded topical 5FUs currently on the market: (1) Respondent’s Efudex; (2) Dermik’s Carac; and (3) Allergan, Inc.’s Fluoroplex. Two generic companies, Spear Pharmaceuticals and Taro Pharmaceuticals U.S.A., Inc., market generic equivalents of Efudex, and Respondent also markets an authorized generic of the drug. Efudex sales have been almost completely displaced by sales of the three generic

versions of the drug. Branded Carac is priced directly against the three generics of branded Efudex. Post-acquisition, Respondent's market share in the topical 5FU market would be over 50 per cent.

V. ENTRY CONDITIONS

8. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of topical drug development times and U.S. Food and Drug Administration approval requirements take more than two years. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a new entrant would likely be insufficient to justify the time and investment necessary to enter.

VI. EFFECTS OF THE ACQUISITION

9. 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 Respondent and Sanofi and creating a monopoly in the market for BenzaClin thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating actual, direct, and substantial competition between Respondent and Sanofi in the market for topical 5FUs and reducing the number of competitors in the market for topical 5FUs thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices.

VII. VIOLATIONS CHARGED

10. The Acquisition Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 3, 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 December, 2011, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL: