

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman  
J. Thomas Rosch  
Edith Ramirez  
Julie Brill  
MaureenK. Ohlhausen

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In the Matter of )  
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NOVARTIS A G, ) Docket No. C-4364  
a corporation. )  
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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Novartis AG ("Novartis"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Fougera Holdings Inc. ("Fougera"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the of the Clayton Acts amended, 15 U.S. § 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. RESPONDENT

1. Respondent Novartis is a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation, with its headquarters address located at Lichtstrasse 35, Basel, Switzerland, V8 CH4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, NY 10169.

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 ACQUIRED COMPANY

3. Fougera Holdings Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 60 Baylis Road, Melville, NY 11747. The ultimate parent entity of Fougera Holdings Inc. is Fougera S.C.A. SICAR.

## III. THE PROPOSED ACQUISITION

4. Pursuant to an Agreement and Plan of Merger (“Acquisition Agreement”) dated May 1, 2012, Novartis, through its subsidiary, Sandoz Inc., proposes to acquire Fougera for approximately \$1.525 billion (the “Acquisition”).

## IV. THE RELEVANT MARKETS

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

- a. generic cefepime topical solution;
- b. generic lidocaine-prilocaine cream;
- c. generic metronidazole topical gel; and

share. The Acquisition would increase the Herfindahl-Hirschman Index concentration by 1,474 points to 6,568 points.

8. Generic lidocaine-prilocaine cream is used as a local anesthetic to treat intact skin and to relieve pain from injections and surgery. Lidocaine-prilocaine is available in both 30 gram tubes and packages containing five 5 gram tubes ("5-5 tubes"). The 5-5 tubes are used only in hospitals, while the 30 gram tubes are prescribed directly to patients for home use. Fougera, Hi-Tech Pharmaceuticals ("Hi-Tech"), and Novartis are the only U.S. suppliers of 30 gram tubes, with market shares of approximately 50 percent, 47 percent, and 3 percent, respectively. The Acquisition would increase the Herfindahl-Hirschman Index concentration in that market by 300 points to 5,018 points, and have Hi-Tech as the only competitor to the combined Novartis/Fougera. Only Fougera and Novartis offer the 5-tubes, with respective market shares of approximately 83 percent and 17 percent. The Acquisition would therefore create a monopoly in that market.

9. Generic metronidazole topical gel is used to treat inflamed papules and pustules of rosacea, a condition that causes chronic redness of facial skin. Taro Pharmaceutical Industries ("Taro") is the market leader with approximately 43 percent market share, Fougera has approximately 36 percent market share, Novartis has approximately 19 percent market share, and G & W has approximately 2 percent market share. The Acquisition would increase the Herfindahl-Hirschman Index concentration by 1,368 points to 4,878 points.

10. Solaraze is a branded drug sold by Fougera that is used to treat actinic keratosis. No companies currently market a generic version of the drug, diclofenac sodium gel, in the United States. Novartis is best positioned to be the first generic entrant into this market.

## VI. ENTRY CONDITIONS

11. Entry into the relevant markets described in Paragraphs 5 and 6 would not

- a. by eliminating actual, direct, and substantial competition between Novartis and Fougere and reducing the number of competitors in the markets for the sales of generic cacipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel,