

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Jon Leibowitz, Chairman**
 J. Thomas Rosch
 Edith Ramirez
 Julie Brill
 Maureen K. Ohlhausen

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)	
In the Matter of)	
)	
NOVARTIS AG,)	Docket No. C-4364
a corporation.)	
)	
_____)	

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 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. 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 calcipotriene topical solution;
- b. generic lidocaine-prilocaine cream;
- c. generic metronidazole topical gel; and
- d. generic diclofenac sodium gel.

6. 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.

V. THE STRUCTURE OF THE MARKETS

7. Generic calcipotriene topical solution is used to treat chronic, moderately severe scalp psoriasis. Only three companies offer generic calcipotriene topical solution in the United States: Novartis, Fougera, and G & W Laboratories (“G & W”). Novartis leads the market with a 67 percent share. G & W accounts for 22 percent, while Fougera represents an 11 percent

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 Pharmaceutical Co. (“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 leave Hi-Tech as the only competitor to the combined Novartis/Fougera. Only Fougera and Novartis offer the 5-5 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 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 drug development times and U.S. Food and Drug Administration approval requirements are likely to take at least two years.

VII. EFFECTS OF THE ACQUISITION

12. 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 Novartis and Fougera and reducing the number of competitors in the markets for the sales of generic calcipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel, thereby: (1) increasing the likelihood that Novartis will be able to unilaterally exercise market power in these markets; (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating potential competition between Novartis and Fougera in the market for the sale of diclofenac sodium gel and reducing the number of competitors in the future, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of a generic diclofenac sodium gel product; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial price competition that would have resulted from an additional supplier of a diclofenac sodium gel product.

VIII. VIOLATIONS CHARGED

13. The Acquisition Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

14. 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 thirteenth day of July, 2012 issues its Complaint against said Respondent.

By the Commission.

Janice Podoll Frankle
Acting Secretary

SEAL: