

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeney

<hr/>)
In the Matter of)
)
VALEANT PHARMACEUTICALS)
INTERNATIONAL, INC.)
a corporation;)
)
and)
)
PRECISION DERMATOLOGY, INC.)
a corporation.)
)
)
<hr/>)

Docket No. C-4477

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 Valeant Pharmaceuticals International, Inc. (“Valeant”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent Precision Dermatology, Inc. (“Precision”), 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 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. RESPONDENTS

1. Respondent Valeant is a corporation organized, existing, and doing business under and by virtue of the laws of the Province of British Columbia, Canada, with its headquarters at 2150 St. Elzear Blvd. West, Laval, Quebec, H7L 4A8, Canada. Valeant's U.S. headquarters is located at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey, 08807.

2. Respondent Precision is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters at 900 Highland Corporate Drive, Suite #203, Cumberland, Rhode Island, 02864.

3. 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 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

4. Pursuant to an Agreement and Plan of Merger dated January 31, 2014, Valeant proposes to acquire Precision for approximately \$475 million, plus an additional \$25 million payable upon a sales-based milestone (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. 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 development, license, manufacture, marketing, distribution, and sale of the following pharmaceutical products:

- a. branded and generic single-agent topical tretinoins for the treatment of acne; and
- b. generic Retin-A and/or the individual strengths and formulations of generic Retin-A.

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

7. Branded and generic single-agent topical tretinoins are used to treat acne vulgaris, commonly known as acne. Valeant currently manufactures and markets the branded single-agent topical tretinoins Retin-A, Retin-A Micro, and Atralin, as well as generic Retin-A and generic Retin-A Micro. Currently, Valeant markets its generic Retin-A through a profit sharing

arrangement with Spear Pharmaceuticals (“Spear”). Precision markets the branded single-agent topical tretinoin Retin-X. In addition, Precision markets generic Retin-A through a profit sharing arrangement with Rouses Point Pharmaceuticals, LLC (“Rouses Point”). The only other suppliers of single-agent topical tretinoin are Mylan with a branded product, Avita, and Actavis, with one strength of generic Retin-A. Currently, Valeant’s branded and generic single-agent topical tretinoin market share is 70%, and Precision’s market share is 12%. Absent a remedy, the merged entity would have a market share in excess of 80% and the transaction will result in a substantial increase in concentration in the already highly concentrated market for branded and generic single-agent topical tretinoin. Specifically, the transaction would increase the Herfindahl-Hirschman Index (“HHI”) by 1680, from 5368 to a post-merger total of 7048.

8. Generic Retin-A is the generic version of Valeant’s branded tretinoin product, Retin-A. The market for generic Retin-A is highly concentrated with only three current suppliers: (1) Precision, which holds an Abbreviated New Drug Application (“ANDA”) for five strengths of generic Retin-A and distributes its products through Rouses Point; (2) Valeant, which holds the New Drug Application (“NDA”) for Retin-A and distributes five strengths of an “authorized” generic through Spear; and (3) Actavis, which markets only one strength of generic Retin-A cream. Absent a remedy, the transaction would result in a monopoly in all but the one strength of generic Retin-A cream for which the number of suppliers would be reduced from three to two.

V. ENTRY CONDITIONS

9. 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. *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. EFFECTS OF THE ACQUISITION

10. 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 Valeant and Precision and reducing the number of significant competitors in the market for branded and generic single-agent topical tretinoin for the treatment of acne, including the only two meaningful providers of branded products, thereby increasing the likelihood that: (1) Valeant would be able to unilaterally exercise market power in this market; and (2) customers would be forced to pay higher prices; and

- b. by eliminating actual, direct, and substantial competition between Valeant and Precision and reducing the number of significant competitors in the market for generic Retin-A thereby increasing the likelihood that: (1) Valeant would be able to unilaterally exercise market power in this market; and (2) customers would be forced to pay higher prices.

VII. VIOLATIONS CHARGED

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

12. 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 third day of July, 2014 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: