ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Valeant Pharmaceuticals International, Inc. and Precision Dermatology, Inc.
File No. 141-0101

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Valeant Pharmaceuticals International, Inc. ("Valeant"), which is designed to remedy the anticompetitive effects of Valeant's acquisition of Precision Dermatology, Inc. ("Precision").

The proposed 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 proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an Agreement and Plan of Merger dated January 31, 2014, Valeant plans to acquire Precision for approximately $475 million in cash, plus an additional $25 million milestone payment upon the achievement of certain sales targets (the "Proposed Acquisition"). Both parties sell topical pharmaceutical products in the United States. 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 competition in U.S. markets for (1) branded and generic single-agent topical tretinoins for the treatment of acne and (2) generic Retin-A and/or the individual strengths and formulations of generic Retin-A. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition. Specifically, under the terms of the Consent Agreement, Valeant would be required to divest all of Precision's rights and assets related to (1) Tretin-X and (2) generic Retin-A. Valeant has proposed Actavis, Inc. ("Actavis") as the buyer of the Tretin-X assets and Matawan Pharmaceuticals, LLC ("Matawan Pharmaceuticals") as the buyer of the generic Retin-A assets.

II. The Products and Structure of the Markets

A. Branded and Generic Single-Agent Topical Tretinoins

Valeant's proposed acquisition of Precision would significantly increase concentration in the single-agent topical tretinoin market. Single-agent topical tretinoins are one of three kinds of retinoids, a class of chemical compounds used to treat acne vulgaris, commonly known as acne. Single-agent topical tretinoins are not reasonably interchangeable with the other two kinds of retinoids, adapalene and tazarotene, because they are used to treat patients with a different severity of acne. Tretinoins are viewed as more efficacious but more abrasive than adapalenes and less abrasive but less efficacious than tazarotenes.

The branded and generic single-agent topical tretinoin market includes both branded and generic tretinoins. Unlike pharmaceutical markets in which the branded product no longer competes with generics once multiple generics enter, branded versions of single-agent topical tretinoins continue to compete with each other and their generic versions. Although generics contain the same molecule as the brands, many dermatologists believe that prescribing a branded product allows them to know precisely which delivery vehicles their patients are using, and hence what might be the cause of any skin irritation that may arise. As a result, even years after generic entry into this market, many dermatologists still prescribe branded tretinoins, and Valeant and Precision continue to invest in promotion and marketing of their branded products.

Valeant currently manufactures and markets branded Retin-A, Retin-A Micro, and Atralin, as well as generic Retin-A and Retin-A Micro. Currently, Valeant markets its generic Retin-A through a profit sharing arrangement with Spear Pharmaceuticals ("Spear"). Precision markets Tretin-X, as well as generic Retin-A through a profit sharing arrangement with Rouses Point Pharmaceuticals, LLC ("Rouses Point"). The only other suppliers of single-agent topical tretinoins are Mylan, with its branded product, Avita, and Actavis, with one strength of generic Retin-A. Currently, Valeant accounts for approximately 70% of single-agent topical tretinoin sales, and Precision has a share of approximately 12%. Spear, Rouses Point, Mylan and Actavis account for the remaining 18% of the market. Unremedied, the Proposed Acquisition will consolidate the two most significant suppliers of single-agent topical tretinoins, and would increase the Herfindahl-Hirschman Index concentration ("HHI") by 1680, from 5368 to a post-merger total of 7048. Valeant's post-acquisition market share in the single-agent topical tretinoin market would grow to over 80%.

B. Generic Retin-A

In addition, Valeant's proposed acquisition of Precision would consolidate two leading suppliers of generic Retin-A. Although generic Retin-A products are part of the single-agent topical tretinoin market, generic Retin-A products compete particularly closely with each other and, therefore, also comprise a separate relevant market. Generic Retin-A is offered in a variety of strengths and formulations. Three suppliers currently offer generic Retin-A products: (1) Precision, which holds an Abbreviated New Drug Application ("ANDA") for generic Retin-A and distributes five strengths and formulations of its generic Retin-A products through Rouses Point; (2) Valeant, which holds the New Drug Application ("NDA") for Retin-A and distributes through an "authorized" generic arrangement with Spear the same strengths and formulations as Precision's generic Retin-A; and (3) Actavis, which markets one of the five formulations of generic Retin-A currently on the market. Since retail pharmacies typically carry each of these strengths and formulations in order to be able to fill the full range of requested prescriptions, each strength and formulation may constitute a distinct product market. Absent a remedy, the Proposed Acquisition will result in a monopoly for four of the five strengths of generic Retin-A, and a duopoly for the only other formulation (the 0.025% cream), for which the post-acquisition market share would increase to nearly 80% and the HHI would rise from 3534 to 6568.

III. Entry

Entry into the manufacture and sale of both branded and generic single-agent topical tretinoins and generic Retin-A generally or for any given strength/formulation would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including U.S. Food and Drug Administration ("FDA") approval, is costly and lengthy. Industry participants also note that expertise and facilities associated with manufacturing topical products are sufficiently specialized that a relatively small number of firms participate in such markets.

IV. Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers for the manufacture and sale of both branded and generic single-agent topical tretinoins and generic Retin-A and/or the individual strengths and formulations of generic Retin-A by eliminating actual, direct, and substantial competition between Valeant and Precision in these markets. With respect to branded and generic single-agent topical tretinoins, the Proposed Acquisition would likely result in unilateral anticompetitive effects. Evidence gathered during the course of the investigation demonstrates that there is close competition between Valeant's and Precision's branded tretinoin products in terms of pricing and promotional activities. Although generic tretinoins provide some competitive constraint on branded tretinoin pricing, there is a sufficient degree of direct competition between Valeant's and Precision's branded products that Valeant will likely have an incentive to increase the price of branded single-agent topical tretinoins if the Proposed Acquisition takes place. Since many managed care organizations incentivize the use of generic tretinoin over branded tretinoin, the competition between Precision's and Valeant's branded products has benefitted consumers primarily in the form of promotional couponing. The Proposed Acquisition would likely allow Valeant to raise prices by reducing its couponing and other promotional activity for Tretin-X.

For the generic Retin-A products, the Proposed Acquisition would give Valeant a monopoly in four of five strengths and formulations of generic Retin-A, a duopoly for the only other strength, and would combine the two largest suppliers of generic Retin-A overall. In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition, due to a decrease in the number of independent competitors in the markets at issue. The combination of these products at Valeant results in even greater concentration in already highly concentrated markets and would likely result in significantly higher prices for all strengths of generic Retin-A.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each of the relevant product markets. Pursuant to the Consent Agreement, the parties are required to divest Precision's rights and assets related to Tretin-X to Actavis, and its rights and assets related to generic Retin-A to Matawan Pharmaceuticals. Further, the proposed Consent Agreement requires Precision to assign to Actavis and Matawan Pharmaceuticals its contract manufacturing agreement with DPT Laboratories Ltd. ("DPT") for the divested assets. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

Actavis is well-suited to acquire Tretin-X because of its current presence in the dermatology field, and the fact that it already markets a branded antibiotic, Doryx, that is also used to treat acne vulgaris. Actavis is a multinational pharmaceutical company headquartered in Ireland that employs approximately 19,200 individuals. In 2013, the company generated $8.7 billion in worldwide revenue. Actavis develops, manufactures, markets, sells, and distributes branded, generic, branded generic, biosimilar, and over-the-counter pharmaceutical products. Currently, Actavis offers forty-five branded pharmaceutical products and approximately 250 generic pharmaceutical product lines in the United States. Actavis employs a significant dermatology sales force.

Since Actavis will step into Precision's existing contract manufacturing relationship with DPT for the production of Tretin-X, no transfer of manufacturing will be necessary for the proposed divestiture and Actavis will be able to compete immediately following the acquisition in the single-agent topical tretinoin market.

Matawan Pharmaceuticals is an acceptable purchaser of the generic Retin-A assets and will be able to replicate Precision's role in that market. Under the proposed divestiture, Matawan Pharmaceuticals will purchase the generic Retin-A assets, but little else will change as the products will continue to be manufactured by DPT and marketed by Rouses Point. Since Matawan Pharmaceuticals will use Precision's already-existing contract manufacturing relationship with DPT for the production of generic Retin-A, no transfer of manufacturing will be necessary.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Actavis and Matawan Pharmaceuticals are not acceptable acquirers of the divested assets, or that the manner of the divestitures is not acceptable, the parties must unwind the sale of rights to Actavis and Matawan Pharmaceuticals, and divest the Tretin-X and generic Retin-A assets to Commission-approved acquirers within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the Products if the parties fail to divest them as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Valeant and Precision to take all action to maintain the economic viability, marketability, and competitiveness of the products to be

divested until such time that they are transferred to Commission-approved acquirers. The Order also requires that Valeant and Precision transfer all confidential business information, including customer information related to the divestiture products, to Actavis and Matawan Pharmaceuticals.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.