ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Akorn, Inc., File No. 141-0162

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Akorn, Inc. ("Akorn") that is designed to remedy the anticompetitive effects in the market for generic injectable rifampin ("generic rifampin") resulting from Akorn's acquisition of VersaPharm Inc. ("VersaPharm"). Under the terms of the proposed Consent Agreement, Akorn is required to divest its Abbreviated New Drug Application ("ANDA") for generic rifampin to Watson Laboratories, Inc. ("Watson"), a wholly-owned subsidiary of Actavis plc.

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, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order ("Order").

Pursuant to an Agreement and Plan of Merger dated May 9, 2014, Akorn plans to acquire all of VPI Holdings Corp., the parent company of VersaPharm, for approximately $324 million (the "Proposed Acquisition"). 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 future competition in the sale of generic rifampin. The proposed Consent Agreement will remedy the alleged violations by preserving the future competition that would otherwise be eliminated by the Proposed Acquisition.

The Product and Structure of the Market

The Proposed Acquisition would reduce the number of future suppliers in the market for generic rifampin. Generic rifampin is an antibacterial medication used as a first-line treatment to kill or prevent the growth of tuberculosis. There are currently three generic drug companies with approved ANDAs for rifampin: VersaPharm, Mylan/Agila, and Bedford. Akorn is one of a limited number of firms that have a generic rifampin product in development and an ANDA under review by the U.S. Food and Drug Administration ("FDA"). As a result, the Proposed Acquisition would significantly reduce the number of future suppliers for generic rifampin.

Entry

Entry into the market for generic rifampin would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, is costly and lengthy. In addition, the expertise and facilities required to manufacture injectable products is sufficiently specialized that only a limited number of firms are capable of participating in such markets. The stability and sterility requirements specific to

manufacturing injectable pharmaceuticals present a number of problems and costs that discourage new entry or expansion in the market for generic rifampin.

Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers by eliminating the future competition that would otherwise have occurred when Akorn's generic rifampin product entered the market. 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 price of generic pharmaceutical products decreases with new entry even after a number of suppliers has entered the market. Further, customers have confirmed that, in pharmaceutical markets that can experience significant manufacturing problems and shortages, such as the market for generic rifampin, the entry of a fourth, fifth, sixth, or even subsequent generic competitor produces more competitive prices than if fewer suppliers are available to them.

The Proposed Acquisition would eliminate significant future competition between Akorn and VersaPharm. 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 market for generic rifampin. Absent the Proposed Acquisition, the presence of Akorn as an additional competitor likely would have allowed customers to negotiate lower prices, as well as secure supply in times of product shortages. Thus, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for generic rifampin, absent a remedy.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Akorn is required to divest its rights related to generic rifampin to Watson. Akorn must accomplish this divestiture no later than ten days after the Proposed Acquisition is consummated.

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 Watson is not an acceptable acquirer of the divested asset, or that the manner of the divestiture is not acceptable, the parties must unwind the sale of rights to Watson and divest the asset to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the asset if the parties fail to divest it as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. The Order requires Akorn to take all action necessary to maintain the economic viability, marketability, and competitiveness of the asset to be divested. Akorn must assist Watson in securing FDA approval for the pending ANDA. Akorn must also provide transitional services to assist Watson in setting up its generic rifampin manufacturing process, which includes conveying all know-how, data, and other information necessary to transfer its

manufacturing capabilities. To allow Watson to enter the market while it validates its manufacturing process, the Order requires Akorn to provide Watson with a supply of product.

The Commission has agreed to appoint F. William Rahe from Quantic Regulatory Services, LLC to act as an interim monitor to assure that Akorn expeditiously complies with all of its obligations and perform all of its responsibilities pursuant to the Consent Agreement. To ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Akorn to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

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.