ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Hikma Pharmaceuticals PLC
File No. 111-0051, Docket No. C-4320

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Hikma Pharmaceuticals PLC ("Hikma") that is designed to remedy the anticompetitive effects of Hikma's acquisition of certain assets from Baxter Healthcare Corporation, Inc. ("Baxter"). Under the terms of the proposed Consent Agreement, Hikma would be required to divest to X-Gen Pharmaceuticals, Inc. ("X-Gen") all of Hikma's rights and assets relating to its generic injectable phenytoin and generic injectable promethazine products.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an Asset Purchase Agreement dated October 29, 2010, Hikma proposes to acquire Baxter's generic injectable pharmaceutical business in a transaction valued at approximately $111.5 million ("Proposed Acquisition"). The assets to be sold include chronic pain, anti-infective, and anti-emetic products, along with Baxter's Cherry Hill, New Jersey manufacturing facility and Memphis, Tennessee warehouse and distribution center. The Commission's Complaint alleges 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 the U.S. markets for generic injectable phenytoin and generic injectable promethazine. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of generic suppliers in each of the relevant markets. The number of generic injectable suppliers has a direct and substantial effect on pricing.

Phenytoin is an anti-convulsant drug used to control seizures and prevent them during or after surgery. In 2009, sales of injectable phenytoin totaled $1.5 million. The branded version of injectable phenytoin is no longer sold in the United States. The market for generic injectable phenytoin is highly concentrated; currently only Hikma, Baxter, and Hospira, Inc. ("Hospira") sell the product in the United States. The acquisition of Baxter's injectable business by Hikma would therefore reduce the number of suppliers of injectable phenytoin from three to two.

Generic injectable promethazine is used to relieve or prevent some types of allergies or allergic reactions, to prevent and control motion sickness, nausea, vomiting, and dizziness, and to help people go to sleep and control their pain or anxiety before or after surgery. Sales of generic injectable promethazine totaled $17 million in 2009. The market for generic injectable promethazine is highly concentrated. Only three companies currently sell generic injectable promethazine in the United States: Hikma, Baxter, and Hospira. Hospira's competitive significance in this market is limited because it only offers a premium-priced pre-filled syringe, while Hikma and Baxter offer lower priced ampules and vials that appeal to a broader range of customers. A fourth company has approval to sell generic injectable promethazine in the United States and has historically offered the product, but it is not currently manufacturing the product and its re-entry date is currently unknown. Thus, the acquisition would result in a market with only one low-cost competitor.

Entry

Entry into the markets for the manufacture and sale of generic injectable phenytoin and generic injectable promethazine 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 generic drug development times and regulatory requirements, including Food and Drug Administration approval, takes at least two years. In addition to the regulatory hurdles facing a potential entrant, manufacturing difficulties in producing generic injectable products, combined with the small size of the markets in question, makes additional entry unlikely to occur.

Effects

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic injectable phenytoin and generic injectable promethazine. In generic injectable pharmaceuticals markets, price generally decreases as the second, third, or fourth competitors enter. Thus, reducing the number of competitors to two and one in each market, respectively, would cause anticompetitive harm to consumers in these U.S. markets by increasing the likelihood that consumers would pay higher prices.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets by requiring Hikma to divest certain rights and assets related to generic injectable phenytoin and generic injectable promethazine to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

The proposed Consent Agreement remedies the competitive concerns the acquisition raises by requiring Hikma to divest its generic injectable phenytoin and generic injectable promethazine products to X-Gen, which will purchase all rights currently held by Hikma. X-Gen is a New York-based generic injectable pharmaceutical company with 40 active products and an active product development pipeline. With its experience in generic injectable markets and strong ties to manufacturing partners, X-Gen is expected to replicate the competition that would otherwise be lost with the Proposed Acquisition.

If the Commission determines that X-Gen is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale to X-Gen and divest the phenytoin and promethazine product lines, within six months of the date the Order becomes final, to a Commission-approved acquirer. The Commission may appoint a trustee to divest the products if Hikma fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Hikma to take all action to maintain the economic viability, marketability, and competitiveness of the products until such time as they are transferred to a Commission-approved acquirer. In addition, the parties must supply X-Gen with phenytoin and promethazine pursuant to a supply agreement while Hikma transfers the manufacturing technology to X-Gen or a third-party manufacturer of X-Gen's choice.

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.