

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT
In the Matter of Hikma Pharmaceuticals PLC
*File No. 151-0198***

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 resulting from Hikma’s acquisition of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, “Roxane”) from Boehringer Ingelheim Corporation (“BI”). Under the terms of the proposed Consent Agreement, Hikma must divest all of its rights and assets related to 5 mg, 10 mg, and 20 mg generic prednisone tablets and to generic lithium carbonate capsules to Renaissance Acquisition Holdings LLC (“Renaissance”), and to divest all marketing rights and ownership interests in generic flecainide tablets to Unimark Remedies Ltd (“Unimark”).

The Commission has placed the proposed Consent Agreement 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 a Stock Purchase Agreement dated July 28, 2015, Hikma proposed to acquire 100% of the issued and outstanding shares of Roxane for approximately \$2.65 billion. On February 10, 2016, the purchase price was reduced to approximately \$2 billion (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 current competition in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsules market, and future competition in the market for generic flecainide tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that the Proposed Acquisition would otherwise eliminate.

I. The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of current suppliers in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and for generic lithium carbonate capsules, and reduce the number of future suppliers in the market for generic flecainide tablets.

Prednisone is a corticosteroid that prevents the release of substances in the body that cause inflammation. It is used to treat arthritis, allergies, and other conditions. Prednisone is also prescribed as an immunosuppressant medication. Generic prednisone is available in six tablet strengths: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, and 50 mg. Hikma and Roxane both market three of the six tablet strengths: 5 mg, 10 mg, and 20 mg. In addition to Hikma and Roxane,

Endo International plc, Allergan, Inc., and Jubilant Cadista Pharmaceuticals, Inc. also offer 5 mg, 10 mg, and 20 mg generic prednisone tablets in the United States.

Lithium carbonate capsules are prescribed for the treatment of manic episodes of bipolar disorder and for the maintenance treatment of bipolar disorder. Lithium therapy reduces the frequency of manic episodes and diminishes the intensity of episodes when they occur. In addition to Hikma and Roxane, two other firms currently supply generic lithium carbonate capsules in the United States: Glenmark Pharmaceuticals Ltd. and Camber Pharmaceuticals Inc.

Flecainide acetate is an antiarrhythmic drug used to prevent and treat abnormally fast heart rhythms. Four firms currently market generic flecainide tablets: Roxane, Amneal Pharmaceuticals, ANI Pharmaceuticals, Inc., and Citron Pharma. Hikma owns the U.S. marketing rights to a generic flecainide in development at Unimark Remedies Ltd. Hikma is one of few suppliers that can enter the United States market in the near future.

II. Entry

Entry into the relevant markets 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 approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

III. Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Hikma and Roxane in the markets for 5 mg, 10 mg, and 20 mg generic prednisone tablets and in the generic lithium carbonate capsule market. Market participants characterize both generic prednisone tablets and generic lithium carbonate capsules as commodity products, and prices are typically inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisition would combine two of five companies offering the 5 mg, 10 mg, and 20 mg strengths of generic prednisone tablets, and two of four firms offering generic lithium carbonate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisition likely would harm consumers by eliminating future generic competition that would otherwise have occurred in the generic flecainide market if Hikma and Roxane remained independent. The Proposed Acquisition would likely harm competition by eliminating an additional independent entrant in the market for generic flecainide. Customers view the price of this pharmaceutical product as less competitive than it would be in a market with more participants, including Hikma. Thus, absent a remedy, the Proposed Acquisition would likely cause U.S. consumers to pay significantly higher prices for generic flecainide tablets.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition by requiring Hikma to divest all its rights and assets relating to 5 mg, 10 mg, and 20 mg generic prednisone and those relating to generic lithium carbonate capsules to Renaissance. Established in 2010 and based in Newtown, Pennsylvania, Renaissance is a privately held pharmaceutical company that manufactures and markets both generic and branded prescription drugs in the United States. In addition, the proposed Consent Agreement requires Hikma to return its rights to market generic flecainide tablets in the United States to Unimark, along with its equity interest in Unimark.

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 Renaissance is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Hikma to unwind the sale of rights to Renaissance and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee should the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Hikma supply Renaissance with 5 mg, 10 mg, and 20 mg generic prednisone tablets and with generic lithium carbonate capsules for eighteen months while Hikma transfers the manufacturing technology to Renaissance's facility. The proposed Order also requires Hikma to provide a back-up supply of active pharmaceutical ingredient for generic prednisone tablets should the need for it arise. To ensure the success of these divestitures, the proposed Order requires Hikma to provide transitional services to assist Renaissance in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Hikma, and advice and training from knowledgeable employees of the parties. In addition, to ensure that Hikma complies with the terms of the Consent Agreement, the Commission has appointed Owen Richards of Quantic Regulatory Services, LLC as the Interim Monitor.

To remedy competitive concerns raised by the acquisition in the market for generic flecainide tablets, the proposed Order requires Hikma to divest its approximately 23% ownership interest in Unimark and to return to Unimark all rights it has to commercialize generic flecainide tablets in the United States. Unimark has selected another firm, Bion Pharma, of Princeton, New Jersey, to market generic flecainide tablets in the United States upon the product's approval by the FDA.

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.