ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Hikma Pharmaceuticals PLC and C.H. Boehringer Sohn AG & Co. KG
File No. 151-0044

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Hikma Pharmaceuticals PLC ("Hikma") and C.H. Boehringer Sohn AG & Co. KG ("Boehringer") that is designed to remedy the anticompetitive effects that otherwise would have resulted from Hikma's proposed acquisition of forty-nine Abbreviated New Drug Applications ("ANDAs") from Ben Venue Laboratories, Inc. ("Ben Venue"), a subsidiary of Boehringer, in five generic injectable pharmaceutical markets. Boehringer recently exited the markets related to these ANDAs when it ceased its manufacturing and other operations through Ben Venue. Under the terms of the proposed Consent Agreement, Hikma is required to divest to Amphastar Pharmaceuticals, Inc. ("Amphastar") the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection.

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, or make final the Decision and Order ("Order").

Pursuant to a Sale and Purchase Agreement dated December 4, 2014 ("Proposed Acquisition"), Hikma proposes to acquire forty-nine ANDAs from Boehringer for approximately $5 million. 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 markets for acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection in the United States. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

I. The Relevant Products and Structure of the Markets

The relevant products are all generic versions of injectable pharmaceutical products. Generic versions of these products are usually launched after a branded product's patents expire, or a generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. Sometimes, however, a branded injectable drug manufacturer may choose to lower its price and compete against generic versions of the drug, in which case it would be a participant in the generic drug market.

The relevant products at issue and the structure of each of the relevant markets is as follows:

- Acyclovir sodium injection is an antiviral drug used to treat chicken pox, herpes, and other related infections. Three firms, Boehringer, Fresenius Kabi AG ("Fresenius"), and AuroMedics Pharma LLC ("AuroMedics"), currently have ANDAs for this drug that have been approved by the U.S. Food and Drug Administration ("FDA"). Only Fresenius and AuroMedics currently supply acyclovir sodium injection to the market. Hikma and one other firm are likely to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of acyclovir sodium injection from five to four.

- Diltiazem hydrochloride injection is a calcium channel blocker and antihypertensive used to treat hypertension, angina, and arrhythmias. There are four firms that currently have FDA-approved ANDAs for diltiazem hydrochloride injection, Hikma, Boehringer, Hospira, Inc. ("Hospira"), and Akorn, Inc. ("Akorn"), but only Hikma, Hospira, and Akorn currently supply the market. No other firms are likely to enter the market in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of diltiazem hydrochloride injection from four to three.

- Famotidine injection treats ulcers and gastroesophageal reflux disease. Three firms currently sell the vial presentation of famotidine injection, Hikma, Fresenius, and Mylan N.V. Boehringer has an FDA-approved ANDA for famotidine injection vials, but had no sales of the drug in 2014. No other companies appear to be poised to enter the market in the near future. The Proposed Acquisition would therefore reduce the number of likely future suppliers of famotidine injection from four to three.

- Prochlorperazine edisylate injection is an antipsychotic used to treat schizophrenia and nausea. Boehringer owned virtually the entire market for prochlorperazine edisylate injection in 2013, but it exited the market in mid-2014. Since that time, Heritage Pharmaceuticals Inc. has assumed all sales of prochlorperazine edisylate injection. Hikma is the only other company that has an FDA-approved ANDA for prochlorperazine edisylate injection, but it is not currently supplying the market. Another firm has prochlorperazine edisylate injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of prochlorperazine edisylate injection from four to three.

- Valproate sodium injection is used to treat epilepsy, seizures, bipolar disorder, anxiety, and migraine headaches. There are two firms that currently supply valproate sodium injection in the market, Hikma and Fresenius. Boehringer has an FDA-approved ANDA for valproate sodium injection but exited the market in July 2014. Another firm has valproate sodium injection in its development pipeline and anticipates achieving FDA approval of its ANDA in the near future. Thus, the Proposed Acquisition would reduce the number of likely future suppliers of valproate sodium injection from four to three.

II. Competitive Effects

The transaction will reduce competition by decreasing the number of future suppliers in in each of these markets; in generic pharmaceutical products, prices generally decrease as the number of competing generic suppliers increases. In addition, the injectable pharmaceutical industry generally, and the generic products at issue in this investigation in particular, are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities of, and contributed to price increases of, several of the generic injectable products impacted by this transaction. By reducing the number of likely future competitors in these markets, the Proposed Acquisition will likely create a direct and substantial anticompetitive effect on prices for each of the relevant products, absent the remedies required by the proposed Consent Agreement.

In each of the relevant markets, either Hikma or Boehringer, or both, currently do not supply an existing generic product. For markets in which Hikma is not a current competitor, it is likely to become one in the near future. Boehringer has recently exited each of these markets, but, absent the Proposed Acquisition, it would have had the incentive to sell these ANDAs to a third-party supplier who would likely bring these products to market. Hikma, which already has an approved ANDA or is likely to soon achieve FDA approval for an ANDA in each of the five relevant markets at issue, lacks that incentive, and thus, customers would be deprived of the price decreases that likely would have accompanied third-party entry into each of these concentrated markets.

III. Entry

Entry into each of these generic injectable product markets will not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years.

IV. The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Hikma is required to divest the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection, and valproate sodium injection to Amphastar. Hikma must accomplish these divestitures and relinquish its rights no later than ten days after the acquisition.

Amphastar is a global pharmaceutical company based in Rancho Cucamonga, California and has over 1,200 employees worldwide. The company owns five pharmaceutical manufacturing facilities and produces a variety of branded and generic pharmaceutical products. Amphastar manufactures and sells sixteen injectable drug products in the United States, as well as a broad range of other pharmaceutical dosage formulations, including emulsions, suspensions, jellies, and lyophilized products. The company sells most of its products through long-standing

relationships with major group purchasing organizations, drug wholesalers, and retailers in the United States. With its experience in generic markets, and in injectable products in particular, Amphastar is expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Amphastar is not an acceptable acquirer, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Amphastar and divest the products 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 products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Boehringer to maintain the economic viability, marketability, and competitiveness of the assets to be divested until they are transferred to Hikma, and requires Hikma to do the same until such time as they are transferred to a Commission-approved acquirer. The Order also requires that the parties transfer all confidential business information, regulatory, formulation, and manufacturing reports, as well as provide access to employees who possess or are able to identify such information. Because the products related to the Boehringer (Ben Venue) ANDA assets have already exited the market, the Order does not require a transitional supply 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.