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,

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