

**ANALYSIS OF PROPOSED CONSENT ORDER  
TO AID PUBLIC COMMENT**  
*In the Matter of Hospira, Inc., and Mayne Pharma Limited*  
*File No. 071-0002, Docket No. C-4182*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Hospira Inc. (“Hospira”) and Mayne Pharma Ltd. (“Mayne”), which is designed to remedy the anticompetitive effects of Hospira’s acquisition of Mayne. Under the terms of the Consent Agreement, the companies would be required to assign and divest to Barr Pharmaceuticals, Inc. (“Barr”) the Mayne rights and assets necessary to manufacture and market the following generic injectable pharmaceuticals: (1) hydromorphone hydrochloride (“hydromorphone”); (2) nalbuphine hydrochloride (“nalbuphine”); (3) morphine sulfate (“morphine”); (4) preservative-free morphine; and (5) deferoxamine mesylate (“deferoxamine”).

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) 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 a Scheme Implementation Agreement dated September 20, 2006, Hospira intends to acquire all of the outstanding shares of Mayne for approximately \$2 billion. Both parties manufacture and sell generic pharmaceuticals in the United States. 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 FTC Act, as amended, 15 U.S.C. § 45, in the markets for the manufacture and sale of the following generic injectables: (1) hydromorphone; (2) nalbuphine; (3) morphine; (4) preservative-free morphine; and (5) deferoxamine (“the Products”). The proposed Consent Agreement remedies the alleged violations by replacing in each of these markets the lost competition that would result from the acquisition.

### **The Products and Structure of the Markets**

Hospira’s proposed acquisition of Mayne would strengthen Hospira’s position in generic injectable pharmaceuticals and provide it with a stronger pipeline of generic products. Injectable pharmaceuticals are not close substitutes for oral drugs because they are used when a patient is unable to ingest pills or capsules or when an immediate onset of action is required and the patient cannot wait for the treatment to pass through the gastrointestinal system. The companies overlap in a number of generic injectable pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in five of the overlap markets.

The transaction would reduce the number of competing generic suppliers in five already concentrated markets. When the number of suppliers of a generic is small, the number of

suppliers has a direct and substantial effect on generic pricing, as each additional supplier can have a competitive impact on the market. Because there are (or would be) multiple generic equivalents for each of the Products absent the proposed acquisition, the branded versions would not significantly constrain the generics' pricing.

For one of the generic injectable products at issue, hydromorphone, Hospira and Mayne currently are two of only three suppliers offering the product. In the remaining four markets, Mayne is one of a limited number of suppliers capable of, and in the process of, entering these markets. As a result, the proposed acquisition would eliminate important future competition in these markets.

Injectable hydromorphone is a narcotic opioid analgesic used to relieve moderate to severe pain, both acute and chronic, and is classified by the U.S. Drug Enforcement Administration ("DEA") as a Schedule II narcotic. The branded product, Dilaudid-HP, is manufactured and sold by Abbott Laboratories Inc. In 2006, sales of generic injectable hydromorphone exceeded \$39 million. Only three companies compete in the generic injectable hydromorphone market: Hospira, Baxter Healthcare Corp. ("Baxter"), and Mayne. Hospira is the market leader with a market share of approximately 60 percent. Mayne and Baxter are the only other suppliers, with market shares of 25 percent and 15 percent, respectively. After Hospira's acquisition of Mayne, Hospira's market share would increase from 60 percent to approximately 85 percent, and Baxter would be the only other competitor.

Nalbuphine is an injectable opioid analgesic used to relieve moderate to severe pain in patients. Hospira currently is the only supplier of generic injectable nalbuphine in the United States. Mayne is in the process of entering this market and is one of a limited number of firms capable of entering this market in a timely manner. The proposed acquisition would eliminate Mayne's entry into the injectable nalbuphine market.

Injectable morphine is a widely-used opioid analgesic for the treatment of moderate to severe, acute and chronic pain, and is classified by the DEA as a Schedule II narcotic. Hospira is the leading supplier of injectable morphine, and provides a full-line of preservative and preservative-free morphine products in various strengths, sizes, and delivery mechanisms. Baxter and Amphastar Pharmaceuticals, Inc. are the only other suppliers of injectable morphine in the United States. Mayne is in the process of entering this market and is one of a limited number of suppliers capable of entering this market in a timely manner. The proposed acquisition would eliminate Mayne's entry into the injectable morphine market. Absent the proposed transaction, Mayne would have been the only competitor to Hospira for the 50 mg/ml strength presentations of injectable morphine.

Injectable preservative-free morphine, unlike injectable morphine, is used when the drug is delivered to the intrathecal or epidural space next to the nerves in a patient's spine. Currently, only Hospira and Baxter sell preservative-free morphine in the United States in the manner of generic suppliers. Mayne is in the process of entering this market and is one of a limited number

of suppliers capable of entering this market in a timely manner. The proposed transaction would eliminate Mayne's entry into the injectable preservative-free morphine market.

Injectable deferoxamine is an iron chelator used to treat acute iron poisoning or chronic iron overload. Hospira and Teva Pharmaceutical Industries Ltd. are the only suppliers of generic injectable deferoxamine in the United States. Mayne is in the process of entering this market and is well-positioned to enter this market in a timely manner. The proposed acquisition would eliminate Mayne's entry into the injectable deferoxamine market.

## **Entry**

Entry into the markets for the manufacture and sale of the Products would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Developing and obtaining U.S. Food and Drug Administration ("FDA") approval for the manufacture and sale of each of the Products takes at least two (2) years due to substantial regulatory, technological, and intellectual property barriers.

## **Effects of the Acquisition**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic injectable hydromorphone, generic injectable nalbuphine, generic injectable morphine, generic injectable preservative-free morphine, and generic injectable deferoxamine. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. Here, the evidence shows that, given the small number of suppliers, the prices of the generic pharmaceutical product at issue decrease with the entry of each additional competitor. Evidence gathered during our investigation indicates that anticompetitive effects – whether unilateral or coordinated – are likely to result from the decrease in the number of independent competitors in the markets at issue that would be a consequence of the proposed acquisition.

In the market for generic injectable hydromorphone, the proposed acquisition would leave only two current competitors: the combined firm and one other company. The evidence indicates that the presence of three independent competitors in these markets allows customers to negotiate lower prices, and that a reduction in the number of competitors would allow the merged entity and the other market participant(s) to raise prices.

The competitive concerns in the market for generic injectable hydromorphone can be characterized as both unilateral and coordinated in nature. Certain conditions in the relevant market may reduce the ability of suppliers to reach and maintain an agreement on price. For example, bids to GPOs typically specify prices and rebates for an array of drugs and presentations, and there are long term contracts. Nevertheless, the weight of the evidence leads to the conclusion that the transaction will increase the likelihood of coordination. The transparency of awards by GPOs makes coordination among the suppliers, especially customer

allocation, more likely to occur, because deviation from an agreement would be relatively easy to detect. Also, the fact that there will be only two suppliers after the proposed acquisition is an important consideration in evaluating the likelihood of coordination.

The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects. With fewer bidders, the probability of winning a given bid is higher and the incentives to bid aggressively are lower. With transactions that lead to a significant decrease in the number of bidders for a given drug, such as the instant one, a significant increase in the price charged to customers is likely to result. Such effects are likely to be particularly large in the market for generic injectable hydromorphone, where there would be only two competitors after Hospira's acquisition of Mayne.

The proposed acquisition also would cause significant anticompetitive harm to consumers by eliminating potential competition between Hospira and Mayne in the markets for the manufacture and sale of generic injectable nalbuphine, generic injectable morphine, generic injectable preservative-free morphine, and generic injectable deferoxamine. In each of these markets, there are no more than three current suppliers, and Mayne is poised to enter in the near future. Mayne's independent entry into these markets would likely result in lower prices. The proposed transaction would eliminate that independent entry, and hence would leave prices at levels that are higher than would prevail absent the acquisition.

### **The Consent Agreement**

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Hospira and Mayne are required to divest certain rights and assets related to the relevant products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that the parties assign and divest all of the Mayne rights and assets for the Products to Barr.

The acquirers of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Barr is a reputable generic injectable pharmaceutical manufacturer and is well-positioned to compete effectively in each of the relevant product markets. Following its recent acquisition of Pliva d.d., Barr markets several injectable pharmaceutical products in the United States and has multiple manufacturing facilities, an established sales organization, FDA and DEA regulatory expertise, and a robust injectable product pipeline. Moreover, Barr will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, and good

reputation, Barr is well-positioned to replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that Barr is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Barr is not acceptable, the parties must unwind the sale and divest the Products within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Hospira and Mayne to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Hospira and Mayne.

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC (“Quantic”) to oversee the asset transfer and to ensure Hospira and Mayne’s compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Hospira and Mayne to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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 Consent Agreement or to modify its terms in any way.