





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

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.