

II. RESPONDENTS

5. Respondent Hospira is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 275 North Field Drive, Lake Forest, Illinois 60045. Hospira is engaged in the development, manufacture, marketing, sale, and distribution of generic injectable pharmaceutical products and drug delivery devices.

6. Respondent Mayne is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Australia, with its headquarters address at Level 3, 390 St. Kilda Road, Melbourne, Victoria 3004, Australia, and with the address of the principal place of business of Mayne Pharma (USA) Inc., its United States subsidiary, at 650 From Road, 2nd Floor, Mack-Cali Centre II, Paramus, New Jersey 07652. Mayne is engaged in the development, manufacture, marketing, sale, and distribution of generic injectable pharmaceutical products.

7. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

8. Pursuant to a Scheme Implementation Agreement (the “Agreement”), Hospira proposes to acquire all of the outstanding shares of Mayne (the “Acquisition”). The transaction is valued at approximately \$2 billion.

IV. THE RELEVANT MARKETS

9. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, manufacture, and sale of the following generic injectable pharmaceutical products:

- a. hydromorphone hydrochloride;
- b. morphine sulfate (with preservatives);
- c. preservative-free morphine sulfate;
- d. nalbuphine hydrochloride; and
- e. deferoxamine mesylate.

10. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

V. THE STRUCTURE OF THE RELEVANT MARKETS

11. Hydromorphone hydrochloride is an opioid analgesic agent used to relieve moderate to severe acute and chronic pain. Hydromorphone hydrochloride is classified by the DEA as a Schedule II narcotic. Currently, Hospira, Baxter Healthcare Corp. (“Baxter”), and Mayne are the only suppliers of generic hydromorphone hydrochloride in the United States. The Acquisition would leave only Hospira and Baxter in this market, and increase Hospira’s market share to over 85 percent. The Herfindahl-Hirschman Index (“HHI”) would increase by 3,000 points, resulting in a post-acquisition HHI of 7,450 points.

12. Morphine sulfate is an opioid analgesic agent used in the treatment of moderate to severe acute and chronic pain. Morphine sulfate also is classified by the DEA as a Schedule II narcotic. Hospira is the leading supplier of generic morphine sulfate with a full-line of product presentations and strengths. Baxter and Amphastar Pharmaceuticals, Inc. are the only other suppliers of morphine sulfate 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 Acquisition would eliminate Mayne’s entry into the morphine sulfate market.

13. Preservative-free morphine sulfate, unlike morphine sulfate, 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 sulfate like 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 Acquisition would eliminate Mayne’s entry into the preservative-free morphine sulfate market.

14. Nalbuphine hydrochloride is an opioid analgesic agent used to relieve moderate to severe pain in patients. Hospira currently is the only supplier of nalbuphine hydrochloride 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 Acquisition would eliminate Mayne’s entry into the nalbuphine hydrochloride market.

15. Deferoxamine mesylate 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 deferoxamine mesylate 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 Acquisition would eliminate Mayne’s entry into the deferoxamine mesylate market.

VI. ENTRY CONDITIONS

16. Entry into each of the relevant product markets described in Paragraph 9 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval for the manufacture and sale of each of these products takes at least two years due to substantial regulatory, technological, and intellectual property barriers.

VII. EFFECTS OF THE ACQUISITION

17. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of 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 following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Hospira and Mayne, and reducing the number of competitors in the market for the manufacture and sale of generic injectable hydromorphone hydrochloride thereby: (1) increasing the likelihood that Hospira will be able to unilaterally exercise market power in this market, (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating potential competition between Hospira and Mayne in the markets for the manufacture and sale of generic injectable morphine sulfate, preservative-free morphine sulfate, nalbuphine hydrochloride, and deferoxamine mesylate, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Mayne's products in these markets, and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Mayne's independent entry into the markets.

VIII. VIOLATIONS CHARGED

18. The Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

19. The Acquisition described in Paragraph 8, if consummated, would constitute a violation of 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighteenth day of January, 2007, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: