

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: D. P. M., C
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M LAN LABORATORIES, INC.,) D J N . C-4200
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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Mylan Laboratories, Inc. (“Mylan”), a corporation subject to the jurisdiction of the Commission, has agreed to certain assets of E. Merck oHG and its controlled entity Merck KGaA (collectively “Merck”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

II. RESPONDENTS

4. Respondent Mylan is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

5. Respondent Merck is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at 250 Frankfurter Street, Darmstadt, Germany. Merck markets and sells generic products in the United States through its U.S. subsidiary, Genpharm L.P., located at 150 Motor Parkway, Suite 309 in Hauppauge, New York 11788. Merck also has an agreement with Par Pharmaceutical Companies, Inc. (“Par”), whereby Merck manufactures a number of generic products and Par markets them in the United States. Merck receives a royalty payment on Par’s sales of these products. Merck is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

6. 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

7. On May 12 and 13, 2007, Mylan and Merck entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Mylan proposes to acquire Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries for approximately \$6.6 billion.

I. THE RELEVANT MARKETS

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

- a. acebutolol hydrochloride capsules;
- b. flecainide acetate tablets;
- c. guanfacine hydrochloride tablets;
- d. nifedipine hydrochloride capsules; and
- e. sotalol hydrochloride AF tablets.

9. 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 line of commerce.

. THE STRUCTURE OF THE MARKETS

10. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Acebutolol is a beta blocker used to treat hypertension. The market for generic acebutolol capsules is already highly concentrated with a pre-acquisition HHI of 5,158 points. The proposed merger would raise the HHI concentration by 4,842 points and create a monopoly in the acebutolol market.

11. Generic flecainide tablets are produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (“Roxane”), Barr Pharmaceuticals Inc. (“Barr”), and Ranbaxy Pharmaceuticals Inc. (“Ranbaxy”). Flecainide is an anti-arrhythmia drug used to treat heart problems. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. Combined, Barr and Ranbaxy account for less than 5 percent market share. The proposed acquisition would increase the market concentration by 2,344 points, resulting in a post-merger HHI of 6,369 points.

12. Guanfacine, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (“Watson”), Merck/Par, Actavis Group hf. (“Actavis”), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States. Mylan, Merck/Par, Watson and Actavis, however, are the only suppliers of the 2 mg formulation of guanfacine. The proposed acquisition would raise the current HHI concentration in the generic guanfacine tablet market from 3,824 points to 4,908 points.

13. Nicardipine is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (“Teva”) are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed acquisition would raise the HHI from its current level of 4,170 points to 7,631 points and leave Teva as the only competitor to the combined Mylan/Merck in the generic nicardipine market.

14. Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is lead by Apotex Inc. (“Apotex”). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007.

I. ENTR CONDITIONS

15. Entry into the relevant product markets described in Paragraph 8 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant markets are relatively small and in decline, limiting sales opportunities for any potential new entrant.

