

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
 Pamela Jones Harbour
 Jon Leibowitz
 William E. Kovacic
 J. Thomas Rosch

In the Matter of

TEVA PHARMACEUTICAL INDUSTRIES LTD.,
a corporation;

and

IVAX CORPORATION,
a corporation.

Docket No. C-4155

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 Teva Pharmaceutical Industries Ltd. (“Teva”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire IVAX Corporation (“IVAX”), 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

1. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Teva and IVAX individually and collectively.
4. “LA” means long-acting formulation.

II. RESPONDENTS

5. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel, with its office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva's principal subsidiary in the United States, Teva Pharmaceuticals USA, Inc., is located at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva, among other things, is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

6. Respondent IVAX is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 4400 Biscayne Boulevard, Miami, Florida 33137. IVAX, among other things, is engaged in the research, development, manufacture, and sale of generic 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. On July 25, 2005, Teva and IVAX entered into an Agreement and Plan of Merger (the "Merger Agreement") whereby Teva proposes to acquire all of the issued and outstanding shares of IVAX in a transaction valued at approximately \$7.4 billion (the "Acquisition").

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 manufacture and sale of the following generic pharmaceutical products:

- a. Amoxicillin clavulanate potassium;
- b. Cefaclor LA tablets;
- c. Pergolide mesylate tablets;
- d. Estazolam tablets;
- e. Leuprolide acetate injection kits;
- f. Nabumetone tablets;
- g. Amoxicillin;
- h. Propoxyphene hydrochloride capsules;
- i. Nicardipine hydrochloride capsules;
- j. Flutamide capsules;
- k. Clozapine tablets;
- l. Tramadol/Acetaminophen tablets;

- m. Glipizide & metformin hydrochloride tablets;
- n. Calcitriol injectables; and
- o. Cabergoline tablets.

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 MARKETS

11. Amoxicillin clavulanate potassium (“amox/clav”) is a commonly-prescribed penicillin antibiotic used to treat infections. Currently, Teva, IVAX, Sandoz Inc. (“Sandoz”), and Ranbaxy Pharmaceuticals, Inc. (“Ranbaxy”) are the only suppliers of various formulations of generic amox/clav in the United States. Teva and IVAX, however, are the only suppliers of the 600 mg powder formulation of generic amox/clav. The Acquisition would leave only Teva, Sandoz, and Ranbaxy in the generic amox/clav market, and increase Teva’s market share in all formulations to over 50 percent. The Herfindahl-Hirschman Index (“HHI”) would increase by 1,360 points, resulting in a post-acquisition HHI of 4,438 points.

12. Teva dominates the U.S. market for the manufacture and sale of generic cefaclor LA tablets, with a share of over 65 percent. Cefaclor LA tablets are cephalosporin antibiotics. The only other supplier of this product is IVAX. The Acquisition would create a monopoly in this market, and increase the HHI concentration by 4,422 points, resulting in a post-acquisition HHI of 10,000 points.

13. The market for the manufacture and sale of generic pergolide mesylate tablets is highly concentrated, with a pre-acquisition HHI of 6,568 points. Pergolide mesylate tablets are used to treat Parkinson’s disease. Only Teva and IVAX offer this product in the United States. The Acquisition would create a monopoly in this market and increase the HHI concentration by 3,432 points, resulting in a post-acquisition HHI of 10,000 points.

14. Teva is the leading supplier in the market for the manufacture and sale of generic estazolam tablets in the United States, with 52 percent of the market. Estazolam tablets are used to treat seizure disorders. IVAX and Watson Pharmaceuticals, Inc. are the only other suppliers of this product. The Acquisition would create a duopoly, with Teva accounting for approximately 65 percent of the generic estazolam tablet market. The HHI would increase by 1,352 points to a post-acquisition HHI of 5,450 points.

15. Leuprolide acetate is an injectable drug used to treat prostate cancer. Teva is the leading supplier in the U.S. market for the manufacture and sale of generic leuprolide acetate. IVAX and Sandoz are the only other suppliers of this product. The Acquisition would create a duopoly, with Teva accounting for over 50 percent of the market. The HHI would increase 100 points to a post-acquisition HHI of 5,002 points.

16. Teva is the leading supplier in the market for the manufacture and sale of generic nabumetone tablets, with a share of over 60 percent. Nabumetone tablets are used to treat inflammation. IVAX and Sandoz are the only other suppliers of generic nabumetone tablets in the United States. The Acquisition would create a duopoly in this market, and increase the HHI concentration by 360 points, resulting in a post-acquisition HHI of 5,338 points.

17. Teva dominates the U.S. market for the manufacture and sale of generic amoxicillin. Amoxicillin is a penicillin antibiotic used to treat infections. Teva, IVAX, Ranbaxy, Stada Pharmaceuticals, Inc., and Sandoz are the only suppliers of various formulations of generic amoxicillin in the United States. Teva, IVAX, and Ranbaxy, however, are the only suppliers of the 200 mg and 400 mg oral suspensions and the 875 mg tablet formulations of the drug. The Acquisition would increase Teva's market share in the amoxicillin formulations to over 55 percent, and increase the HHI concentration by 110 points, resulting in a post-acquisition HHI of 4,094 points.

18. The market for the manufacture and sale of generic propoxyphene hydrochloride capsules in the United States is highly concentrated, with a pre-acquisition HHI of 4,696 points. Propoxyphene hydrochloride capsules are analgesics used to relieve severe pain. Currently, Teva, IVAX, Mylan Pharmaceuticals ("Mylan"), and Qualitest Pharmaceuticals, Inc. ("Qualitest") are the only suppliers in this market. After the Acquisition, Mylan and Qualitest would be the only competitors to Teva in this market, and the HHI concentration would increase by 663 points to a post-acquisition HHI of 5,359 points.

19. The market for the manufacture and sale of generic nifedipine hydrochloride capsules is highly concentrated. Nifedipine hydrochloride capsules are used to treat heart conditions. Teva, IVAX, Mylan, and Par Pharmaceutical Companies, Inc. ("Par") are the only suppliers of this product in the United States. After the Acquisition, Mylan and Par would be the only competitors to Teva in this market, and the HHI would increase by 216 points to a post-acquisition HHI of 3,592 points.

20. Teva and IVAX are the two leading suppliers of generic flutamide capsules in the United States, with 26 percent and 36 percent of the market, respectively. Flutamide capsules are used to treat cancer. Currently, Sandoz and Barr Pharmaceuticals, Inc. ("Barr") are the only other suppliers of this product. After the Acquisition, Teva would control over 60 percent of the generic flutamide capsule market, and Sandoz and Barr would be the only remaining competitors to Teva. The HHI would increase 1,015 points to a post-acquisition HHI of 3,702 points.

21. IVAX, Mylan, and Caraco Pharmaceuticals Ltd. ("Caraco") are the only suppliers in the U.S. market for the manufacture and sale of generic clozapine tablets. Clozapine tablets are used to treat psychotic and maniac disorders. Teva has FDA approval to sell this drug, and has recently begun offering it to customers. In the absence of its pending acquisition of IVAX,

Teva would have offered lower prices to attract customers and ultimately caused the market price of generic clozapine tablets to decrease. The Acquisition would leave only the combined Teva/IVAX entity, Mylan, and Caraco as suppliers in this market.

22. Par, IVAX, and Caraco are currently the only suppliers in the U.S. market for the manufacture and sale of generic tramadol/acetaminophen (“tramadol/apap”) tablets. Tramadol/apap tablets are analgesics used to treat severe pain. Caraco only recently received FDA approval to sell this drug, and has begun offering it to customers. Teva is in the process of entering this market and is the only other supplier capable of entering this market in a timely manner. The Acquisition would eliminate Teva’s planned entry into the generic tramadol/apap tablet market.

23. The market for the manufacture and sale of generic glipizide & metformin hydrochloride tablets is highly concentrated. Glipizide & metformin tablets are blood glucose regulators used to treat type II diabetes. Currently, Teva and Sandoz are the only suppliers of this product in the United States. IVAX 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 IVAX’s planned entry into the generic glipizide & metformin tablet market.

24. Calcitriol is an injectable form of vitamin D that is used in dialysis patients. Teva and American Pharmaceutical Partners, Inc. are the only suppliers in the U.S. market for the manufacture and sale of generic calcitriol. IVAX (through a distribution agreement with Genix Therapeutics, Inc.) is in the process of entering this market as a distributor of the Genix product and is the only supplier capable of entering this market in a timely manner. The Acquisition would eliminate IVAX’s potential entry into the generic calcitriol market.

25. Cabergoline tablets are used to treat Parkinson’s disease. The patent for the branded version of the drug expired in December 2005. Teva and IVAX are in the process of entering this market and are two of a limited number of suppliers who are capable of entering the future market for generic cabergoline tablets.

VI. ENTRY CONDITIONS

26. Entry into each of the relevant product markets described in Paragraph 9 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 FDA approval for the manufacture and sale of these products takes at least two years due to substantial regulatory, technological, and intellectual property barriers.

VII. EFFECTS OF THE ACQUISITION

27. 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 Teva and IVAX, and reducing the number of competitors, in the markets for the manufacture and sale of generic amox/clav, cefaclor LA tablets, pergolide mesylate tablets, estazolam tablets, leuprolide acetate injection kits, nabumetone tablets, amoxicillin, propoxyphene hydrochloride capsules, nifedipine hydrochloride capsules, flutamide capsules, and clozapine tablets thereby: (1) increasing the likelihood that Teva will be able to unilaterally exercise market power in these markets, (2) increasing the likelihood and degree of coordinated interaction between or among competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating potential competition between Teva and IVAX in the markets for the manufacture and sale of generic tramadol/apap tablets, glipizide & metformin hydrochloride tablets, and calcitriol injectables, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Teva's tramadol/apap product, and IVAX's glipizide & metformin and calcitriol products, and (2) increasing the likelihood that the combined entity would delay or eliminate the significant additional price competition that would have resulted from Teva's independent entry into the market for generic tramadol/apap, and IVAX's independent entry into the markets for generic glipizide & metformin and generic calcitriol; and
- c. by eliminating potential competition between Teva and IVAX in the future market for the manufacture and sale of generic cabergoline tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of IVAX's cabergoline product, and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from IVAX's independent entry into the future market for generic cabergoline.

VIII. VIOLATIONS CHARGED

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

29. 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 twentieth day of January, 2006, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: