

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

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

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**In the Matter of**

**TEVA PHARMACEUTICAL INDUSTRIES LTD.,  
a corporation;**

**and**

**BARR PHARMACEUTICALS, INC.,  
a corporation.**

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**Docket No. C-4242**

**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 Barr Pharmaceuticals, Inc. (“Barr”), 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. “Respondent(s)” means Teva and Barr, individually and collectively.

## **II. RESPONDENTS**

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

5. Respondent Barr 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 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Barr 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 July 18, 2008, Teva and Barr entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Teva proposes to acquire all of the issued and outstanding shares of Barr for approximately \$7.4 billion, plus the assumption of approximately \$1.5 billion of net debt, for a total of approximately \$8.9 billion (the “Acquisition”).

## **IV. 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. tetracycline hydrochloride (“HCl”) capsules;
- b. chlorzoxazone tablets;
- c. desmopressin acetate tablets;
- d. metoclopramide HCl tablets;
- e. carboplatin injection;
- f. tamoxifen citrate tablets;

- g. metronidazole tablets;
- h. trazodone HCl tablets;
- i. glipizide/metformin HCl tablets;
- j. cyclosporine capsules;
- k. cyclosporine liquid;
- l. flutamide capsules;
- m. mirtazapine orally disintegrating tablets (“ODT”);
- n. deferoxamine injection;
- o. epoprostenol sodium (freeze-dried powder) injection;
- p. fluoxetine weekly capsules;
- q. norgestimate/ethinyl estradiol 0.025 mg/0.35 mg (“generic Ortho Cyclen”) tablets;
- r. norgestimate/ethinyl estradiol 0.018 mg/0.35 mg, 0.215 mg/0.35 mg, and 0.25 mg/0.35 mg (“generic Ortho Tri-Cyclen”) tablets;
- s. desogestrel/ethinyl estradiol 0.15mg/0.03 mg (“generic Ortho-cept”) tablets;
- t. desogestrel/ethinyl estradiol and ethinyl estradiol 0.15mg/0.02 mg and 0.01 mg (“generic Mircette”) tablets;
- u. levonorgestrel/ethinyl estradiol 0.05 mg/0.03 mg, 0.075 mg/0.04 mg, and 0.125 mg/0.03 mg (“generic Triphasil 28”) tablets;
- v. levonorgestrel and ethinyl estradiol 0.1 mg/0.02 mg (“generic Alesse”) tablets;
- w. norethindrone/ethinyl estradiol 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, and 1 mg/0.035 mg (“generic Ortho-Novum 7/7/7”) tablets;
- x. norethindrone/ethinyl estradiol 1 mg/0.035 mg (“generic Ortho-Novum 1/35”) tablets;

- y. norethindrone acetate/ethinyl estradiol/ferrous fumarate 1.5 mg/0.03 mg/75 mg and 1 mg/0.02 mg/75 mg (“generic Loestrin FE 1.5/30”) tablets;
- z. norethindrone acetate/ethinyl estradiol/ferrous fumarate 1 mg/0.02 mg/75 mg (“generic Loestrin FE 1/20”) tablets;
- aa. norethindrone/ethinyl estradiol 0.4 mg/0.035 mg (“generic Ovcon-35”) tablets;
- bb. norethindrone acetate/ethinyl estradiol/ferrous fumarate 1mg/0.02 mg (“generic Loestrin FE 24”); and
- cc. norgestimate/ethinyl estradiol 0.180mg/0.025 mg, 0.215 mg/0.025 mg, and 0.250 mg/0.025 mg (“generic Ortho Tri-Cyclen Lo 28”).

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.

## **V. THE STRUCTURE OF THE MARKETS**

10. Teva and Barr are the only suppliers of generic tetracycline tablets in the United States. Tetracycline is an old, broad-spectrum antibiotic used primarily to treat acne. The Acquisition would create a monopoly in the market for generic tetracycline in the United States.

11. Chlorzoxazone is a centrally acting muscle relaxant used to treat muscle spasms. Teva and Barr are the only suppliers of generic chlorzoxazone tablets in the United States, with respective markets shares of approximately 42 and 58 percent. The Acquisition would create a monopoly in this market.

12. Teva and Barr are the only manufacturers of generic desmopressin acetate in the United States. Desmopressin acetate tablets are a synthetic replacement for an antidiuretic hormone that reduces urine production during sleep. The Acquisition would create a monopoly in the market for generic desmopressin acetate in the United States.

13. Metoclopramide HCl is a dopamine receptor antagonist used to treat nausea and vomiting, as well as gastroesophageal reflux disease. Barr, Teva, United Research Laboratories/Mutual Pharmaceutical Company (“Mutual”), Qualitest Pharmaceuticals Inc. (“Qualitest”), and Actavis Group (“Actavis”) are the only suppliers of generic metoclopramide HCl in the United States. Teva, Barr, Mutual, and Qualitest, however, are the only suppliers of both the 5 mg and 10 mg strengths of generic metoclopramide HCl. The Acquisition would increase the combined Teva/Barr’s share in both formulations to over 82 percent and increase the Herfindahl-Hirschman Index (“HHI”) concentration by 3,223 points to 6,928 points.

14. Carboplatin injection is a chemotherapy drug used to treat a variety of cancers. Barr, Teva, APP Pharmaceuticals, and Bedford Laboratories (“Bedford”) are the only companies that currently supply generic carboplatin in the United States. The Acquisition would increase the HHI by 1,840 points to 4,652 points and reduce the number of companies offering generic carboplatin injection in the United States from four to three.

15. Tamoxifen is a selective estrogen receptor modulator that is used in the treatment of breast cancer. Teva, Barr, and Mylan Inc. (“Mylan”) are the suppliers of generic tamoxifen citrate tablets. Teva is the market leader with 58 percent of the market. Mylan has 27 percent and Barr has 15 percent. The Acquisition would increase the HHI by 1,740 points to 6,058 points, and would create a duopoly in the U.S. market for generic tamoxifen citrate tablets.

16. Metronidazole is an anti-infective used in the treatment of a variety of bacterial infections. Barr and Teva are the only significant competitors in the market for the manufacture and sale of generic metronidazole tablets. Barr is the market leader with 50 percent of the market, followed by Teva with 39 percent of the market. The Acquisition would increase the HHI by 2,901 points to 7,974 points.

17. Trazodone HCl is an antidepressant with a sedative effect. Four companies currently supply generic trazodone HCl in the United States – Barr, Apotex Group (“Apotex”), Teva, and Watson Pharmaceuticals (“Watson”). Barr is the dominant supplier with close to 71 percent of the market, followed by Apotex with 22 percent and Teva with 4 percent. Watson has less than 3 percent of the market. The Acquisition would increase the HHI by 568 points to 6,118 points.

18. Glipizide/metformin is an anti-diabetes drug that is commonly prescribed as a first line treatment for diabetes. Four companies – Teva, Barr, Sandoz, Inc. (“Sandoz”), and Mylan – currently sell glipizide/metformin HCl tablets in the United States. Sandoz is the market leader with 37 percent of the market. Barr and Teva have roughly equal shares at 25 percent and 26 percent, respectively. The remaining supplier, Mylan, has captured only 12 percent of the market. The Acquisition would reduce the number of competitors in the generic glipizide/metformin HCl tablet market from four to three firms, and would increase the HHI by 1,300 points to 4,114 points.

19. Cyclosporine, in both the liquid and gelcap form, is an immunosuppressant drug used to prevent the rejection of transplanted organs.

20. Abbott Laboratories (“Abbott”), Barr, and Teva, are the three suppliers of generic liquid cyclosporine. Abbott and Barr roughly split the bulk of the market at 45 percent and 44 percent, respectively. The third supplier – Teva – accounts for approximately an 11 percent share of sales. The Acquisition would reduce the number of generic liquid cyclosporine suppliers from three to two firms, and increase the HHI by 968 points to 5,050 points.

21. Sandoz, Abbott, Barr, and Teva are the four current suppliers of cyclosporine gelcaps. Abbott is the market leader with 51 percent of the market. Teva has 20 percent of the

market, and Barr has 21 percent of the market. Sandoz is a much smaller market participant with only 8 percent of the market. The Acquisition would increase the HHI by 840 points to 4,331 points.

22. Flutamide is an anti-androgen drug used to treat prostate cancer. Four suppliers – Teva, Par Pharmaceutical Companies (“Par”), Barr, and Sandoz – supply generic flutamide capsules in the United States. Sandoz is the market leader with 34 percent of the market. Teva has 28 percent and Par has 24 percent of the market. Barr has captured 14 percent of the market. The Acquisition would increase the HHI by 784 points to 3,496 points.

23. Deferoxamine is a chelating agent used to remove excess iron from the body. Hospira Inc. (“Hospira”), Bedford, Teva, and Barr are the four current suppliers of generic deferoxamine injection in the United States. Hospira is the market leader with 73 percent of the market and Bedford and Teva have approximately 11 percent and 12 percent, respectively. Approximately 4 percent of generic deferoxamine sales are currently attributable to Barr. The Acquisition increases the HHI by 96 points to 5,540 points.

24. Mirtazapine ODT is an antidepressant used to treat moderate to severe depression. With 49 percent of the market, Prasco Laboratories is the dominant supplier while Barr and Teva account for 26 percent and 10 percent of the market, respectively. Aurobindo Pharma Ltd. represents 7 percent of the market. Actavis has manufactured and sold generic mirtazapine ODT in the United States, but recently faced manufacturing difficulties and recalled its generic mirtazapine ODT product earlier this year. Thus, the Acquisition would reduce the current number of suppliers of generic mirtazapine ODT from four to three firms, resulting in a post-acquisition HHI of 3,910 points.

25. Oral contraceptives are forms of birth control that contain varying ratios of synthetic estrogen and synthetic progestin to prevent ovulation and pregnancy. In each of the thirteen relevant generic oral contraceptive markets, Teva and Barr are two of a limited number of suppliers or potential entrants.

26. The U.S. market for the manufacture and sale of generic Ortho-Cyclen tablets is already highly concentrated. Watson, Barr, and Teva, are the only suppliers of this generic oral contraceptive in the United States. After the Acquisition, the HHI would increase by 264 points, resulting in a post-acquisition HHI of 5,648 points, and Teva would account for 68 percent of the market.

27. Barr is the leading supplier in the U.S. market for the manufacture and sale of generic Ortho Tri-Cyclen tablets with 49 percent of the market. Watson and Teva are the only other suppliers of this generic oral contraceptive in the United States. The market for generic Ortho Tri-Cyclen is already highly concentrated. After the Acquisition, the HHI would increase by 196 points, resulting in a post-acquisition HHI of 5,002 points, and Teva would account for 51 percent of the market.

28. Barr currently competes in ten additional oral contraceptive markets where Teva is developing competitive products. These ten markets represent generic products that are equivalent to Ortho-Novum 1/35, Ortho-Novum 7/7/7, Ortho-Cept Desogen, Alesse 28, Triphasil 28, Mircette, Ovcon 35, Loestrin FE (1 mg/0.020 mg), Loestrin FE (1.5 mg/0.030 mg), and Loestrin 24 FE. In each of these highly concentrated markets, Barr is one of only two or three suppliers. Teva is one of a limited number of firms developing generic oral contraceptives that would compete in each of these markets, and is well-positioned to enter the markets in a timely manner.

29. Both Teva and Barr are developing generic Ortho Tri-Cyclen Lo 28 tablets. They are two of a limited number of suppliers capable of entering this future generic market in a timely manner.

30. Epoprostenol sodium (freeze-dried powder) injection is used to treat severe primary pulmonary hypertension. Teva is currently the only generic supplier on the market. Barr is one of a limited number of suppliers capable of entering this generic market in a timely manner.

31. The weekly capsule version of fluoxetine is a widely prescribed antidepressant. Barr and Teva are both developing fluoxetine weekly capsules, and are two of a limited number of companies capable of entering this future generic market in a timely manner.

## **VI. ENTRY CONDITIONS**

32. 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 some of the relevant markets are relatively small and in decline, limiting sales opportunities for any potential new entrant.

## **VII. EFFECTS OF THE ACQUISITION**

33. 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 Barr in the market for the manufacture and sale of generic tetracycline HCl capsules, generic chlorzoxazone tablets, and generic desmopressin acetate tablets, thereby: (1) increasing the likelihood that Teva will be

able to unilaterally exercise market power in these markets, and (2) increasing the likelihood that customers would be forced to pay higher prices;

- b. by eliminating actual, direct, and substantial competition between Teva and Barr in the markets for the manufacture and sale of generic metoclopramide HCl tablets, generic carboplatin injection, generic tamoxifen citrate tablets, generic metronidazole tablets, generic trazodone HCl tablets, generic glipizide/metformin HCl tablets, generic cyclosporine capsules, generic cyclosporine liquid, generic flutamide capsules, generic deferoxamine injection, generic mirtazapine ODT, generic Ortho-Cyclen, and generic Ortho Tri-Cyclen, 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 the remaining competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices;
- c. by eliminating potential competition between Teva and Barr in the markets for the manufacture and sale of generic epoprostenol sodium (freeze-dried powder) injection, generic Ortho-Cept tablets, generic Triphasil 28 tablets, generic Alesse tablets, generic OrthoNovum 1/35 tablets, generic OrthoNovum 7/7/7 tablets, generic Loestrin FE 1/20 tablets, generic Loestrin FE 1.5/30 tablets, generic Mircette tablets, generic Loestrin 24 FE, and generic Ovcon-35 tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Barr's generic epoprostenol sodium (freeze-dried powder) injection and Teva's generic Ortho-Cept tablets, generic Triphasil 28 tablets, generic Alesse tablets, generic OrthoNovum 1/35 tablets, generic OrthoNovum 7/7/7 tablets, generic Loestrin FE 1/20 tablets, generic Loestrin FE 1.5/30 tablets, generic Mircette tablets, generic Loestrin 24 FE and generic Ovcon-35 tablets products and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Barr's independent entry into the generic epoprostenol sodium (freeze-dried powder) injection and Teva's independent entry into the generic Ortho-Cept tablets, generic Triphasil 28 tablets, generic Alesse tablets, generic OrthoNovum 1/35 tablets, generic OrthoNovum 7/7/7 tablets, generic Loestrin FE 1/20 tablets, generic Loestrin FE 1.5/30 tablets, generic Mircette tablets, generic Loestrin 24 FE and generic Ovcon-35 tablets markets; and
- d. by eliminating future competition between Teva and Barr in the markets for the manufacture and sale of generic fluoxetine weekly capsules and generic Ortho Tri-Cyclen Lo 28 tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of



Teva's or Barrs'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 Teva's and Barr's independent entry into the markets.

### **VIII. VIOLATIONS CHARGED**

34. The Merger Agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

35. The Acquisition described in Paragraph 7, 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 December, 2008, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL: