# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

William E. Kovacic, Chairman

	Pamela Jones Harbour Jon Leibowitz J. Thomas Rosch		
In the Matter of			
TEVA PHARMAC a corporation;	EUTICAL INDUSTRIES LTD.,	)	Docket No. C-4242
and		) ) )	

BARR PHARMACEUTICALS, INC.,

**COMMISSIONERS:** 

### 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

- g. metronidazole tablets;
- h. trazodone HCl tablets;
- i. glipizide/metformin HCl tablets;
- j. cyclosporine capsules;
- k. cyclosporine liquid;

- 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 fumerate 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. Desmopre

- 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 ar

- 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 mar

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