

**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)	
)	Docket No. C-4171
BARR PHARMACEUTICALS, INC.)	
a corporation.)	
)	

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 Barr Pharmaceuticals, Inc., a corporation subject to the jurisdiction of the Commission, has agreed to acquire Pliva, d.d., 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” means Barr.
4. “Generic nimodipine” means all formulations containing nimodipine.
5. “Generic trazodone” means all formulations of generic trazodone hydrochloride, excluding the 300 mg formulation.

6. “Generic triamterene/HCTZ” means all formulations of generic triamterene with hydrochlorothiazide.

7. “Organ Preservation Solutions” means any product which is used for the preservation of organs intended for transplantation.

II. RESPONDENTS

8. Respondent Barr Pharmaceuticals, Inc. (“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, among other things, generic pharmaceutical products.

9. Pliva d.d. (“Pliva”) is a corporation organized, existing and doing business under and by virtue of the laws of the Republic of Croatia, having its headquarters address at Ulica grad Vukovara 49, 10000 Zagreb, Croatia. Pliva is engaged in the research, development, manufacture and sale of, among other things, generic pharmaceutical products.

10. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation 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

11. On June 27, 2006, Barr announced its intention to acquire all of the issued and outstanding shares of Pliva in a transaction valued at approximately \$2.3 billion (the “Acquisition”).

IV. THE RELEVANT MARKETS

12. 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 pharmaceutical products:

- a. Generic trazodone tablets;
- b. Generic triamterene/HCTZ tablets;
- c. Organ preservation solutions; and
- d. Generic nimodipine soft-gel capsules.

13. 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

14. Trazodone hydrochloride is an antidepressant. Currently, Barr, Pliva, Watson Pharmaceuticals, Inc. (“Watson”), Teva Pharmaceutical Industries Ltd. (“Teva”), and United Research Laboratories/Mutual Pharmaceutical Company (“URL/Mutual”) are the only active suppliers of generic trazodone in the United States. Although there are five suppliers of generic trazodone, not all suppliers are capable of supplying all formulations. For instance, Barr and Pliva are two of only three suppliers of the 150 mg formulation of generic trazodone. The Acquisition would reduce the number of suppliers of generic trazodone from five to four, and increase Barr’s market share to 58 percent. The Herfindahl-Hirschman Index (“HHI”) would increase by 1,272 points, resulting in a post-acquisition HHI of 3,857 points.

15. Triamterene with hydrochlorothiazide is a combination product used to treat high blood pressure. Currently, Barr, Pliva, Watson, Mylan and Sandoz are the only active suppliers of various formulations of generic triamterene/HCTZ tablets in the United States. The Acquisition would reduce the number of suppliers from five to four, and increase Barr’s market share to about 35 percent for all formulations. The HHI would increase by 520 points, resulting in a post-acquisition HHI of 2,961 points.

16. Organ preservation solutions are used during the harvesting of donor organs to flush and preserve the viability of the donor organs prior to transplantation. The market for organ preservation solutions in the United States is highly concentrated. Barr and Pliva have market shares of approximately 60 and 30 percent, respectively, in the \$17 million U.S. market. The rest of the market is divided among several smaller, niche players. The Acquisition would significantly increase concentration in this market, and would leave Barr with a near monopoly share of the organ preservation solution market. The post-acquisition HHI would increase to approximately 8,100 points.

17. Nimodipine is used to treat symptoms resulting from a ruptured blood vessel in the brain. The branded version of this product, Nimotop, is manufactured and sold by Bayer, and the patents for the branded product have already expired. Currently, there are no generic suppliers of nimodipine on the market. Barr, in conjunction with Cardinal Health Inc., plans to introduce generic nimodipine in the fall of 2006. Pliva also plans to introduce generic nimodipine with its partner, Banner Pharmaceuticals Inc. in the same time frame. Pliva and Barr are the only two firms seeking approval to offer generic nimodipine and the only suppliers capable of entering this market in a timely manner. Accordingly, the Acquisition would eliminate potential competition in the generic nimodipine market.

VI. ENTRY CONDITIONS

18. Entry into each of the relevant product markets identified in Paragraph 10 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing the products and obtaining the necessary 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

19. 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 Barr and Pliva, and reducing the number of competitors, in the markets for the manufacture and sale of generic trazodone tablets, generic triamterene/HCTZ tablets, and organ preservation solutions, thereby:
 - (i) increasing the likelihood that Barr will be able to unilaterally exercise market power in these markets;
 - (ii) increasing the likelihood and degree of coordinated interaction between or among competitors; and
 - (iii) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating potential competition between Barr and Pliva in the market for the manufacture and sale of generic nimodipine capsules, thereby increasing the likelihood that Barr would forego or delay the launch of one of the parties' generic nimodipine capsules and increasing the likelihood that Barr would delay or eliminate the substantial additional price competition that would have resulted from one party's independent entry into the future market for generic nimodipine capsules.

VIII. VIOLATIONS CHARGED

20. 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 nineteenth day of October, 2006, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL: