ANALYSIS OF PROPOSED CONSENT ORDER
TO AID PUBLIC COMMENT
In the Matter of Barr Pharmaceuticals, Inc. and Pliva d.d., File No. 061-0217

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Barr Pharmaceuticals, Inc. ("Barr"), which is designed to remedy the anticompetitive effects of its proposed acquisition of Pliva d.d. ("Pliva"). Under the terms of the Consent Agreement, Barr is required to divest to Apotex, Inc. ("Apotex") Barr's generic trazodone and generic triamterene with hydrochlorothiazide ("triamterene/HCTZ") businesses. Further, the Consent Agreement requires Barr to return marketing rights to Pliva's generic nimodipine product in development to its joint venture partner, Banner Pharmacaps, Inc. ("Banner"), or in the alternative, that Barr return marketing rights to its nimodipine product in development to its development partner, Cardinal Health, Inc. ("Cardinal"). Lastly, the Consent Agreement requires Barr to divest Pliva's branded organ preservation solution, Custodiol, to New Custodiol LLC, a company formed for the purpose of marketing and selling Custodiol. The assets for each of the divestitures includes all of the relevant intellectual property, customer lists, research and development information, and regulatory materials. With these divestitures the competition that would otherwise be eliminated through the proposed acquisition of Pliva by Barr will be fully preserved.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an announcement dated June 27, 2006, Barr intends to acquire all of the outstanding shares of Pliva by cash tender offer for approximately $2.5 billion. Both parties manufacture and sell generic pharmaceuticals in the United States. The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate 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 markets for the manufacture and sale of: (1) generic trazodone hydrochloride tablets; (2) generic triamterene/HCTZ tablets; (3) generic nimodipine soft-gel capsules; and (4) organ preservation solutions. The proposed Consent Agreement remedies the alleged violations by replacing in each of these markets the lost competition that would result from the acquisition.

II. The Products and Structure of the Markets

Barr's acquisition of Pliva would reduce the number of current or future competing generic suppliers in the following three pharmaceutical products: trazodone hydrochloride tablets, triamterene/HCTZ tablets and nimodipine soft-gel capsules. The number of generic

suppliers has a direct and substantial effect on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are (or will be) multiple generic equivalents for the three products at issue here, the branded versions do not (or will not) significantly constrain the generics' pricing.

For each of the three generic products at issue here, Barr and Pliva currently are two of a small number of suppliers offering the product or are the only two future competitors.

Trazodone hydrochloride is an antidepressant. The branded product, Desyrel, is manufactured and sold by Apothecon, Inc., and typically sells for fifty times the generic price. Thus, Desyrel does not have a significant effect on pricing for generic trazodone. Sales of generic trazodone were over $53 million in 2005. 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 not all five suppliers are capable of supplying all formulations. For instance, Barr and Pliva are two of only three suppliers of the 150 mg formulation. Because many customers prefer to purchase the 50 mg, 100 mg and 150 mg formulations of generic trazodone from one supplier, the competitive significance of the other two suppliers who do not sell these formulations is limited. Moreover, the acquisition would reduce the number of suppliers of generic trazodone from five to four, and significantly increase Barr's market share to over 64 percent in all formulations.

Triamterene/HCTZ is a combination product used to treat high blood pressure. The branded traimterene/HCTZ product, Maxzide, is manufactured and sold by Mylan Laboratories, Inc. ("Mylan") and is priced more than five times higher than its generic equivalent. Maxzide does not have a significant effect on the pricing of generic triamterene/HCTZ, while the competition between generic producers has a direct and substantial effect on generic triamterene/HCTZ pricing. Currently, Barr, Pliva, Watson, Mylan and Sandoz, Inc. ("Sandoz") are the only active suppliers of various formulations of generic triamterene/HCTZ tablets in the United States. Furthermore, there is evidence that several of these suppliers may have a more limited competitive significance in the market than Barr and Pliva. The proposed acquisition would reduce the number of suppliers from five to four, and would increase Barr's market share to about 35 percent.

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. Although the patent for the branded version of the drug has already expired, there are no generic suppliers of nimodipine on the market. Barr, in conjunction with Cardinal, plans to introduce generic nimodipine in the Fall of 2006. Pliva also has plans to introduce generic nimodipine with its partner, Banner in the same time frame. Pliva and Barr are the only firms in the process of entering this market. The acquisition would, therefore, eliminate future competition between Barr and Pliva and result in a monopoly in the generic nimodipine market.

Barr's acquisition of Pliva would also have an impact in one additional market, organ preservation solutions. These solutions are used during the harvesting of donor organs to flush and preserve the viability of the donor organ 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 this $17 million market. The rest of the market is divided among several smaller, niche players. The acquisition would significantly increase concentration in this market with Barr achieving near monopoly share with approximately 90 percent of the organ preservation solution market.

III. Entry

Entry into manufacture and sale of generic trazodone, generic triamterene/HCTZ, generic nimodipine, and organ preservation solutions 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 each of the relevant products takes at least two years due to substantial regulatory, technological, and intellectual property barriers. In addition to regulatory barriers, penetrating the organ preservation solution market is further hindered by the reluctance of transplant surgeons to switch to a new organ preservation product.

IV. Effects of the Acquisition

The proposed acquisition would cause significant competitive harm to consumers in the U.S. markets for generic trazodone, generic triamterene/HCTZ, and organ preservation solutions by eliminating actual, direct, and substantial competition between Barr and Pliva, by increasing the likelihood that Barr will be able to unilaterally exercise market power, by increasing the likelihood and degree of coordinated interaction between the few remaining competitors, and by increasing the likelihood that consumers will pay higher prices. In these markets, the evidence shows that consumers have obtained lower prices due to the competitive rivalry that exists between market participants. The evidence also shows that as new rivals have entered the markets, consumers have obtained lower prices. The acquisition would also cause significant competitive harm to consumers in the U.S. market for generic nimodipine by eliminating future competition between Barr and Pliva.

V. The Consent Agreement

The proposed Consent Agreement preserves competition in the generic trazodone and triamterene/HCTZ markets by requiring that Barr divest all of the Barr assets for these two products to Apotex within ten days after the acquisition. The proposed Consent Agreement contains several provisions designed to ensure these divestitures are successful. Barr must provide various transitional services to enable Apotex to compete against Barr immediately following the divestiture. These services include providing Apotex with existing inventory of generic trazodone and triamterene/HCTZ, supplying Apotex with generic trazodone and triamterene/HCTZ until Apotex secures FDA approval to manufacture the products for itself in its own facility, and providing Apotex with all technical assistance necessary to obtain any FDA approvals. Apotex is a reputable generic manufacturer and is well-positioned to manufacture and market the acquired products and to compete effectively in those markets. In the United States, Apotex is roughly the tenth-largest generic pharmaceutical company with over 50 products. Moreover, the acquisition by Apotex does not present competitive problems in either the generic trazodone market or the generic triamterene/HCTZ market because it does not currently compete in those markets.

The proposed Consent Agreement preserves the actual and potential competition in the generic nimodipine market by requiring Barr to divest the Pliva nimodipine assets to Banner no later than ten days after the acquisition, or to divest its own nimodipine assets to Cardinal no later than sixty days after the acquisition. Banner and Cardinal are both reputable soft-gel capsule manufacturers and particularly well-positioned to manufacture and market generic nimodipine because they are already manufacturing generic nimodipine soft-gel capsules pursuant to their respective joint ventures with Pliva and Barr.

The proposed Consent Agreement preserves the competition in the organ preservation solution market by requiring Barr to divest the Pliva organ preservation solution business to New Custodiol LLC no later than ten days after the acquisition. The Custodiol product is currently manufactured by a third party, Dr. Franz Kohler Chemie GmbH, who will continue to supply the product to new New Custodiol LLC. New Custodiol LLC is a company that was formed by Pliva's current head of marketing for organ preservation solutions, Mr. Allen Weber, for the purpose of acquiring, marketing and selling Custodiol in the United States. New Custodiol LLC has obtained funding from venture capitalists sufficient to allow it to manufacture and sell Custodiol effectively. The combination of Mr. Allen Weber's industry experience and venture capital backing makes New Custodiol LLC well positioned to acquire Custodiol and to restore the competition that would be lost if the proposed acquisition were to proceed unremedied. If the sale of Pliva's Custodiol is not successful, the Consent Agreement requires that Barr divest its organ preservation solution, ViaSpan, to a Commission-approved acquirer.

If the Commission determines that any of the divestitures or divestees are not acceptable, Barr must rescind the transaction(s) and divest the assets to Commission-approved buyer(s) not

later than six months from the date the Order becomes final. If Barr fails to divest within the six months, the Commission may appoint a trustee to divest the assets.

The proposed remedy also allows for the appointment of an Interim Trustee, experienced in obtaining regulatory approval and the manufacture of pharmaceuticals, to oversee the technology transfer and to assist the divestees in the event of difficulties. As part of the proposed remedy, Barr is required to execute an agreement conferring all rights and powers necessary for the Interim Trustee to satisfy his responsibilities under the Order to assure successful divestitures. The Commission has appointed Mr. William Rahe to be the Interim Monitor and the divestees have consented to his selection. The monitor will ensure that the Commission remains informed about the status of the proposed divestitures and asset transfers.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.