

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT**  
*In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corporation*  
*File No. 061-0139*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Watson Pharmaceuticals, Inc. (“Watson”) and Andrx Corporation (“Andrx”), which is designed to remedy the anticompetitive effects of the acquisition of Andrx by Watson. Under the terms of the proposed Consent Agreement, the companies would be required to: (1) terminate Watson’s marketing agreement with Interpharm Holdings, Inc. (“Interpharm”) and return all of the Watson rights and assets necessary to market generic hydrocodone bitartrate/ibuprofen tablets back to Interpharm; (2) assign and divest the Andrx rights and assets necessary to develop, manufacture, and market generic extended release glipizide (“glipizide ER”) tablets to Actavis Elizabeth LLC, a subsidiary of The Actavis Group hf. (“Actavis”); and (3) divest the Andrx rights and assets necessary to develop, manufacture, and market the eleven generic oral contraceptive products to Teva Pharmaceutical Industries, Inc. (“Teva”).

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) 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 Agreement and Plan of Merger dated March 12, 2006, Watson proposes to acquire all of the outstanding shares of Andrx at a cost of \$25.00 per share. 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceutical products: (1) hydrocodone bitartrate/ibuprofen tablets; (2) glipizide ER tablets; and (3) eleven oral contraceptive products (the “Products”). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

**The Products and Structure of the Markets**

The proposed acquisition of Andrx by Watson would strengthen Watson’s position in generic pharmaceuticals and provide Watson with a stronger pipeline of generic products. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in thirteen of these markets, including eleven oral contraceptive markets.

The transaction would reduce the number of competing generic suppliers in the overlap markets. 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 multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics' pricing.

For four generic products, Watson and Andrx currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors. In nine additional oral contraceptive product markets, both Watson and Andrx have generic products either on the market or in development. Furthermore, there are few firms that are capable of, and interested in, entering these markets. As a result, the proposed acquisition would eliminate important future competition in these markets.

Hydrocodone bitartrate/ibuprofen is a combination of an opioid analgesic agent, hydrocodone bitartrate, and a nonsteroidal anti-inflammatory drug ("NSAID"), ibuprofen and is the generic version of Abbott Laboratories Inc.'s Vicoprofen. Generic hydrocodone bitartrate/ibuprofen tablets are used for the short-term management of acute pain and have been available in the United States since 2003. In 2005, sales of generic hydrocodone bitartrate/ibuprofen exceeded \$62 million. Only three companies compete in the generic hydrocodone bitartrate/ibuprofen market: Watson, Andrx, and Teva. An additional company is in the process of obtaining FDA approval and expects to enter the market once the approval is granted, which is likely to occur in the next two years. Teva is the market leader with approximately 62 percent of the market. Andrx and Watson account for the rest of the market with about 27 percent and 12 percent market share, respectively. After Watson's acquisition of Andrx, Watson's market share would increase from 12 percent to approximately 39 percent, and Teva would be the only remaining competitor to Watson.

Glipizide ER is the generic version of Pfizer's Glucotrol XL. Glipizide ER corrects the effects of type 2 diabetes by stimulating the release of insulin in the pancreas, thereby reducing blood sugar levels in the body. Generic glipizide ER was first introduced in the United States in November 2003. In 2005, sales of generic glipizide ER totaled approximately \$174 million. Watson is the leading supplier in the U.S. market for generic glipizide ER tablets with over 45 percent of the market. Only two other firms, Andrx and Greenstone Ltd. ("Greenstone"), compete with Watson in this market. Andrx and Greenstone have market shares of about 35 percent and 20 percent, respectively. Post-acquisition, Watson's market share would increase to over 80 percent, and Greenstone would be the only other remaining U.S. supplier of generic glipizide ER.

Oral contraceptives are pills taken by mouth to prevent ovulation and pregnancy. They are the most common method of reversible birth control, used by up to 82 percent of women in the United States at some time during their reproductive years. Oral contraceptives contain various formulations of synthetic estrogen and progestin, which are chemical analogues of natural female hormones. Andrx and Teva have an agreement whereby Andrx develops and

manufactures these oral contraceptives and Teva markets the products. Andrx also receives a royalty payment on Teva's sales of the products. In each of the eleven relevant oral contraceptive markets, Watson and Andrx/Teva are two of a limited number of suppliers or potential entrants.

Two of the oral contraceptive products at issue are currently marketed formulations of generic norgestimate/ethinyl estradiol bioequivalent to the branded products, Ortho-Cyclen and Ortho Tri-Cyclen, from Johnson & Johnson. Both products have varying ratios of norgestimate (a progestin) and ethinyl estradiol (an estrogen) that prevent ovulation and pregnancy. Generic formulations of Ortho-Cyclen and Ortho Tri-Cyclen are among the best selling generic oral contraceptives, representing sales of over \$58 million and \$261 million, respectively, in 2005.

Watson, Andrx/Teva, and Barr Pharmaceuticals, Inc. ("Barr") are the only suppliers of generic Ortho-Cyclen and generic Ortho Tri-Cyclen in the United States. After the acquisition, the combined Watson/Andrx would account for 28 percent of the generic Ortho-Cyclen market. Watson is the leading supplier in the U.S. market for the manufacture and sale of generic Ortho Tri-Cyclen tablets. After the acquisition, Watson would account for 56 percent of the market.

Watson currently competes in seven additional oral contraceptive markets where Andrx/Teva is developing competitive products. These seven markets represent generic products that are equivalent to Ortho-cept, Triphasil 28, Alesse, Ortho-Novum 1/35, Ortho-Novum 7/7/7, Loestrin FE (1 mg/0.020 mg), and Loestrin FE (1.5 mg/0.030 mg). In each of these highly concentrated markets, Watson is one of only two or three suppliers. Andrx/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.

Both Watson and Andrx/Teva are developing generic Mircette tablets and generic Ovcon-35 tablets. They are two of a limited number of suppliers capable of entering these future generic markets in a timely manner.

### **Entry**

Entry into the markets for the manufacture and sale of the Products 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 Food and Drug Administration ("FDA") approval for the manufacture and sale of the Products takes at least two (2) years due to substantial regulatory, technological, and intellectual property barriers.

### **Effects**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic hydrocodone bitartrate/ibuprofen tablets, generic glipizide ER tablets, generic Ortho-Cyclen tablets, and generic Ortho Tri-Cyclen tablets. In generic pharmaceutical markets, pricing is heavily influenced by the number of

competitors that participate in a given market. Here, the evidence shows that the price of the generic pharmaceutical product at issue decreases with the entry of each additional competitor. The proposed transaction would eliminate one of at most four competitors in these markets. Evidence gathered during our investigation indicates that anticompetitive effects – whether unilateral or coordinated – are likely to result from a decrease in the number of independent competitors in the markets at issue.

In the markets for generic hydrocodone bitartrate/ibuprofen and generic glipizide ER, the acquisition of Andrx by Watson would leave only two current competitors: the combined firm and one other company. The evidence indicates that the presence of three independent competitors in these markets allows customers to negotiate lower prices, and that a reduction in the number of competitors would allow the merged entity and other market participants to raise prices. Likewise, in the generic oral contraceptive markets, the reduction in the number of competitors from three to two would likely lead to higher prices.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing. The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

The acquisition also would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of 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 mg/0.020 mg) tablets, and generic Loestrin FE (1.5 mg/0.030 mg) tablets, generic Mircette tablets and generic Ovcon-35 tablets by eliminating future competition between Watson and Andrx. In each of these markets, there are no more than three current suppliers, and Andrx is poised to enter in the near future. Andrx's independent entry into these markets likely would result in lower prices. The proposed transaction would eliminate that independent entry and, hence, would leave prices at their current, higher levels.

### **The Consent Agreement**

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Watson and Andrx are required to divest certain rights and assets related to the relevant products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that: (1) Watson terminate its marketing agreement with Interpharm, thereby returning all of its rights to generic hydrocodone bitartrate/ibuprofen back to Interpharm; (2) Andrx divest its rights and assets to generic glipizide ER to Actavis,

including assigning its supply agreement with Pfizer, Inc.; and (3) Andrx divest its rights and assets related to the eleven generic oral contraceptives to Teva, and supply Teva with the products for five years in order for Teva (or its designated contract manufacturer) to obtain all necessary FDA approvals to manufacture and sell the products independently.

The acquirers of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Interpharm specializes in the development, manufacture, and marketing of generic pharmaceutical and over-the-counter products. Interpharm currently manufactures and markets 23 generic pharmaceutical products, and has ten ANDAs under review by the FDA. As a contract manufacturer for Watson's product, Interpharm is an acceptable acquirer of generic hydrocodone bitartrate/ibuprofen because it already has the experience, know-how, and manufacturing infrastructure to produce and sell generic hydrocodone bitartrate/ibuprofen in the United States. Interpharm understands the scientific and technical details of generic hydrocodone bitartrate/ibuprofen because it formulated, developed, and tested the product, and registered the product with the FDA. Moreover, Interpharm will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and experience marketing generic products, Interpharm is well-positioned to replicate the competition that would be lost with the proposed acquisition.

Actavis is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical products, and is an acceptable acquirer of generic glipizide ER. Actavis has an extensive distribution network in the United States, with three major manufacturing facilities and approximately 162 pharmaceutical products in the U.S. market. Actavis also has experience obtaining FDA approvals for generic pharmaceutical products. While Actavis currently does not compete in the market for the divested assets, it has the resources, capabilities, good reputation, and experience necessary to restore fully the competition that would be lost if the proposed Watson/Andrx transaction were to proceed unremedied.

Teva is a global pharmaceutical company specializing in the development, production, and marketing of generic and branded pharmaceuticals. Founded in 1901 and headquartered in Petach Tikva, Israel, Teva employs approximately 25,000 people worldwide and has production facilities in Israel, North America, Europe, and Mexico. Teva and its affiliates are the world's largest generic pharmaceutical company with over 300 generic products, representing \$6.6 billion in estimated 2006 revenue. Because of its current agreement with Andrx, and its well-known reputation and experience in the pharmaceutical industry, Teva is ideally positioned to be a viable, independent competitor in the eleven generic oral contraceptive markets. The acquisition of the eleven generic oral contraceptive products by Teva would effectively restore the competition that would be lost with the proposed merger.

If the Commission determines that either Interpharm or Actavis is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Interpharm, Actavis, or Teva is not acceptable, the parties must unwind the sale and divest the Products within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Watson and Andrx to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Watson and Andrx.

The Commission has appointed Francis J. Civile as the Interim Monitor to oversee the asset transfer and to ensure Watson and Andrx's compliance with all of the provisions of the proposed Consent Agreement. Mr. Civile has over 27 years of experience in the pharmaceutical industry. He is a highly-qualified expert in areas such as pharmaceutical research and development, regulatory approval, manufacturing and supply, and marketing. He has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and government agencies. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Watson and Andrx to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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 Order or to modify its terms in any way.