

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT**

*In the Matter of Teva Pharmaceutical Industries Ltd. and IVAX Corporation  
File No. 051-0214*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Teva Pharmaceutical Industries Ltd. (“Teva”) and IVAX Corporation (“IVAX”), which is designed to remedy the anticompetitive effects of the acquisition of IVAX by Teva. Under the terms of the proposed Consent Agreement, the companies would be required to: (1) assign the IVAX rights and assets necessary to market generic amoxicillin clavulanate potassium (“amox/clav”) to Par Pharmaceutical Companies, Inc. (“Par”); (2) divest the IVAX rights and assets necessary to manufacture and market generic long-acting cefaclor (“cefaclor LA”) tablets to Par; (3) divest the Teva rights and assets necessary to manufacture and market generic pergolide mesylate tablets to Par; (4) divest the IVAX rights and assets necessary to manufacture and market generic estazolam tablets to Par; (5) assign the IVAX rights and assets necessary to market generic leuprolide acetate injection kits to Par; (6) divest the IVAX rights and assets necessary to manufacture and market generic nabumetone tablets to Par; (7) assign the IVAX rights and assets necessary to market generic amoxicillin to Par; (8) divest the IVAX rights and assets necessary to manufacture and market generic propoxyphene hydrochloride capsules to Par; (9) divest the IVAX rights and assets necessary to manufacture and market generic nifedipine hydrochloride capsules to Barr Pharmaceuticals, Inc. (“Barr”); (10) divest the Teva rights and assets necessary to manufacture and market generic flutamide capsules to Par; (11) divest the Teva rights and assets necessary to manufacture and market generic clozapine tablets to Par; (12) divest the Teva assets necessary to manufacture and market generic tramadol/acetaminophen (“tramadol/apap”) tablets to Barr; (13) divest the IVAX rights and assets necessary to manufacture and market generic glipizide and metformin hydrochloride tablets to Barr; (14) assign the IVAX rights and assets necessary to market generic calcitriol injectables to Par; and (15) divest the Teva rights and assets necessary to manufacture and market generic cabergoline tablets to Barr.

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 July 25, 2005, Teva proposes to acquire all of the issued and outstanding shares of IVAX in a transaction valued at approximately \$7.4 billion. 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) amox/clav; (2) cefaclor LA tablets; (3) pergolide mesylate tablets; (4) estazolam tablets; (5) leuprolide acetate injection kits; (6) nabumetone tablets; (7) amoxicillin; (8) propoxyphene hydrochloride capsules; (9) nifedipine hydrochloride capsules; (10) flutamide capsules; (11) clozapine tablets; (12) tramadol/apap tablets; (13) glipizide and metformin hydrochloride tablets; (14) calcitriol injectables; and (15) cabergoline tablets (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 IVAX by Teva would make Teva the world’s largest generic pharmaceutical supplier. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in fifteen of these 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.

In markets for generic pharmaceuticals, a customer often can prevent a price increase either by forcing the incumbent supplier to meet the lower bid of a competitor or by switching to the competitor's product. Therefore, competitors with sufficient capacity, notwithstanding a relatively small current market share, can constrain the price for the generic product and can have a significant competitive impact.

For eleven generic products, Teva and IVAX currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors, and in several, Teva and IVAX are the only generic suppliers.

- ! Amox/clav is a penicillin antibiotic used to treat infections. Annual sales of generic amox/clav are approximately \$676 million. Currently, Teva, IVAX, Sandoz Inc. (“Sandoz”), and Ranbaxy Pharmaceuticals, Inc. (“Ranbaxy”) are the only suppliers of various formulations of generic amox/clav in the United States. Teva has approximately 40 percent of the market, while IVAX has 17 percent. Teva and IVAX, however, are the only suppliers of the 600 mg powder formulation of generic amox/clav. The acquisition would leave only Teva, Sandoz, and Ranbaxy in the generic amox/clav market, and increase Teva’s market share in all formulations to over 50 percent.

- ! In the cefaclor LA tablet and pergolide mesylate tablet markets, Teva and IVAX are the only generic suppliers of these products in the United States. The acquisition would eliminate IVAX as a competitor, create a monopoly in each of these markets, and almost certainly result in higher prices for consumers. Cefaclor LA tablets are cephalosporin antibiotics. Annual sales of generic cefaclor LA tablets are approximately \$2.4 million. Pergolide mesylate tablets are used to treat Parkinson's disease. Annual sales of generic pergolide mesylate tablets are \$19.3 million.
- ! Estazolam tablets are used to treat seizure disorders. Annual sales of generic estazolam tablets are approximately \$2.7 million. Teva, IVAX, and Watson Pharmaceuticals, Inc. are the only suppliers of generic estazolam tablets in the United States. Teva and IVAX have 52 percent and 13 percent of the market, respectively.
- ! Leuprolide acetate is an injectable drug used to treat prostate cancer. Annual sales of generic leuprolide acetate are \$6.2 million. Teva is the leading supplier in this market, accounting for 50 percent of the market. IVAX and Sandoz are the only other suppliers of this product.
- ! Nabumetone tablets are used to treat inflammation. In 2004, total sales of generic nabumetone tablets were \$100 million. Teva is the leading supplier of generic nabumetone tablets in the United States, accounting for over 60 percent of the market. IVAX and Sandoz are the only other suppliers of this product.
- ! Amoxicillin is a penicillin antibiotic used to treat infections. Teva is the leading supplier in the \$143 million market for generic amoxicillin in the United States, with a share of 55 percent. Teva, IVAX, Ranbaxy, Stada Pharmaceuticals, Inc. ("Stada"), and Sandoz are the only suppliers of various formulations of generic amoxicillin. Teva, IVAX, and Ranbaxy, however, are the only suppliers of the 200 mg and 400 mg oral suspensions, and the 875 mg tablet formulations of the drug.
- ! Propoxyphene hydrochloride capsules are analgesics used to relieve severe pain. Annual sales of generic propoxyphene hydrochloride capsules are approximately \$8.3 million. Currently, Teva, IVAX, Mylan Pharmaceuticals ("Mylan"), and Qualitest Pharmaceuticals, Inc. are the only suppliers in this market in the United States.
- ! Nicardipine hydrochloride capsules are used to treat heart conditions. In 2004, total U.S. sales of generic nicardipine hydrochloride capsules were approximately \$674,000. Teva, IVAX, Mylan, and Par are the only generic suppliers in this market.

- ! Flutamide capsules are used to treat cancer. In 2004, total sales for generic flutamide capsules were approximately \$11 million. Teva and IVAX are the leading suppliers in this market, with 26 percent and 36 percent of the market, respectively. Sandoz and Barr are the only other suppliers of this product in the United States.
- Clozapine tablets are used to treat psychotic and maniac disorders. IVAX, Mylan, and Caraco Pharmaceuticals Ltd. (“Caraco”) are the only suppliers in the \$89.6 million U.S. market for generic clozapine tablets. Teva has FDA approval to sell this drug, and has recently begun offering it to some customers. In the absence of its pending acquisition of IVAX, Teva would have offered lower prices to attract customers and ultimately caused the market price of generic clozapine tablets to decrease. The acquisition would leave only the combined Teva/IVAX entity, Mylan, and Caraco as suppliers in this market.

In four product markets, both Teva and IVAX 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.

- Tramadol/apap tablets are analgesics used to treat severe pain. Annual sales of generic tramadol/apap tablets are approximately \$38 million. Currently, Par, IVAX, and Caraco are the only suppliers in this market. Caraco only recently received FDA approval to sell this drug, and has begun offering it to customers. Teva is the only other supplier capable of entering this market in a timely manner. The acquisition would eliminate Teva’s planned independent entry into the generic tramadol/apap tablet market.
- Teva and Sandoz currently are the only suppliers of generic glipizide and metformin hydrochloride tablets, blood glucose regulators used to treat type II diabetes. IVAX is one of a limited number of suppliers capable of entering this market in a timely manner. The acquisition would eliminate IVAX’s entry into the generic glipizide and metformin hydrochloride tablet market.
- Calcitriol is an injectable form of vitamin D that is used in dialysis patients. Annual U.S. sales of generic calcitriol total approximately \$8.3 million. Teva and American Pharmaceutical Partners, Inc., are the only suppliers in the U.S. market for the manufacture and sale of generic calcitriol. IVAX (through a distribution agreement with Genix Therapeutics, Inc.) is the only supplier capable of entering this market in a timely manner. The acquisition would eliminate IVAX’s entry into the generic calcitriol market.

- Cabergoline tablets are used to treat Parkinson's disease. The branded product, Dostinex, is manufactured and sold by Pfizer, Inc. The patent for Dostinex expired in December 2005. Teva and IVAX are two of a limited number of suppliers who are capable of entering the future market for generic cabergoline tablets.

## **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 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. Furthermore, several of the markets at issue are small and declining, making it unlikely that new entry would occur even if prices were to increase by a small but significant amount.

## **Effects**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic amox/clav, cefaclor LA tablets, pergolide mesylate tablets, estazolam tablets, leuprolide acetate injection kits, nabumetone tablets, amoxicillin, propoxyphene hydrochloride capsules, nicardipine hydrochloride capsules, flutamide capsules, and clozapine tablets by eliminating actual, direct, and substantial competition between Teva and IVAX, by increasing the likelihood that Teva will be able unilaterally to exercise market power, by increasing the likelihood and degree of coordinated interaction between or among competitors, and increasing the likelihood that customers 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 cause significant anticompetitive harm to consumers in the U.S. markets for generic tramadol/apap tablets, glipizide and metformin hydrochloride tablets, calcitriol injectables, and cabergoline tablets by eliminating future competition between Teva and IVAX.

## **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, Teva and IVAX are required to divest rights and assets related to the relevant products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, Teva is required to divest all of the rights and assets related to its pergolide mesylate tablet, flutamide capsule, and clozapine tablet products to Par, and all of the rights and assets related to its cabergoline tablet and tramadol/apap tablet products to Barr. Teva is required to divest all of the rights and assets related to IVAX's cefaclor LA tablet, estazolam tablet, nabumetone tablet,

and propoxyphene hydrochloride capsule products to Par, and all of the rights and assets related to IVAX's nicardipine hydrochloride capsule and glipizide and metformin hydrochloride tablet products to Barr. Furthermore, pursuant to the Consent Agreement, Teva is required to assign the rights to IVAX's third party distribution agreements covering amoxicillin, amox/clav, leuprolide acetate injection kit, and calcitriol injectable products to Par.

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.

Par, a reputable generic manufacturer, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Par is the fifth largest generic pharmaceutical company in the United States, with substantial experience in manufacturing, distributing, and marketing generic pharmaceutical products. Par has approximately 187 separate products representing various dosage strengths for over 90 drugs. Moreover, Par 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, Par is well-positioned to replicate the competition that would be lost with the proposed acquisition.

Barr, a reputable generic manufacturer, is also particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Barr is an established U.S. pharmaceutical company that manufactures and markets over 100 different dosage forms and strengths of over 70 different generic pharmaceutical products. Barr has extensive manufacturing, marketing, and sales expertise in U.S. generic pharmaceutical markets, and significant experience transferring assets from other pharmaceutical companies. Barr 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, Barr should be successful in restoring the competition that would be lost if the proposed Teva/IVAX transaction were to proceed unremedied.

If the Commission determines that either Par or Barr is not an acceptable purchaser, or that the manner of the divestiture 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 Teva and IVAX to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA until the acquirers are able to manufacture and sell all formulations and dosages of the Products independently. These transitional services include technology transfer assistance to manufacture

the Products in substantially the same manner and quality employed or achieved by Teva and IVAX. Furthermore, Teva and IVAX are required to supply the acquirers until they receive approval to manufacture the Products on their own

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC (“Quantic”) to oversee the asset transfer and to ensure Teva and IVAX’s compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. 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 Teva and IVAX 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.