## ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Actavis Group hf. and Abrika Pharmaceuticals, Inc. File No. 071-0063

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Actavis Group hf. ("Actavis"), which is designed to remedy the anticompetitive effects of the acquisition of Abrika Pharmaceuticals, Inc. ("Abrika") by Actavis. Under the terms of the proposed Consent Agreement, the company would be required to assign and divest the Abrika rights and assets necessary to manufacture and market generic isradipine capsules to Cobalt Laboratories, Inc. ("Cobalt"), the U.S. subsidiary of Arrow Group.

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 executed on November 20, 2006, Actavis proposes to acquire all of the voting securities of Abrika for \$235 million. 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 generic isradipine capsules. The proposed Consent Agreement will remedy the alleged violation by replacing the lost competition that would result from the acquisition in this market.

Actavis is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical drugs. Headquartered in Iceland, Actavis sells generic pharmaceuticals in over 30 countries and has manufacturing facilities in Europe, the United States, and Asia. Abrika is a Sunrise, Florida based specialty generic pharmaceutical company engaged in the formulation and commercialization of both controlled release and immediate release products.

## **Generic Isradipine Capsules**

Isradipine belongs to a group of drugs known as calcium channel blockers. Calcium is involved in blood vessel contraction, and by blocking calcium, isradipine relaxes and widens the blood vessels, thereby lowering blood pressure, preventing spasms of the blood vessels of the heart and reducing the oxygen needs of the heart muscle. Isradipine is typically prescribed to

patients as a blood pressure lowering medication, and is also used to treat hypertension, ischemia and depression. Generic isradipine was first introduced in the United States in 2006. Sales in that year totaled approximately \$3 million.

Actavis and Abrika are the only two companies selling generic isradipine capsules in the United States. 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 isradipine capsules, the branded version no longer significantly constrains the generic's pricing.

Entry into the market for the manufacture and sale of generic isradipine capsules 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 the relevant market is relatively small and in decline, limiting sales opportunities for any new entrant.

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. market for the manufacture and sale of generic isradipine capsules. The acquisition would eliminate Abrika as a competitor and create a monopoly in the market for the manufacture and sale of generic isradipine capsules. The evidence indicates that the presence of more than one competitor allows customers to negotiate lower prices and that the reduction in the number of competitors in this market would allow the merged entity to unilaterally exercise market power with a resulting increase in prices.

## **The Consent Agreement**

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Actavis and Abrika are required to divest certain rights and assets related to the generic isradipine capsules to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Abrika divest its rights and assets relating to generic isradipine capsules to Cobalt.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser 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.

Cobalt, which specializes in the sale and marketing of generic pharmaceuticals, is the United States arm of the Arrow Group, a private multinational that employs over 700 individuals. The Arrow Group has experience in the development, manufacturing, and sale of pharmaceuticals and has production facilities in Canada, Malta, Australia and Brazil. Cobalt is

an acceptable acquirer of generic isradipine because it has experience in distributing and marketing generic pharmaceutical products in the United States. Currently, the company has received FDA approval for the sale of nine generic products. The acquisition by Cobalt does not present a competitive problem in the generic isradipine market because Cobalt currently does not participate in the market and has no independent plans to enter. With its resources, sales and marketing capabilities, and experience with generic products, Cobalt should be successful in restoring the competition that would be lost if the proposed Actavis/Abrika transaction were to proceed unremedied.

If the Commission determines that Cobalt is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Cobalt is not acceptable, the parties must unwind the sale and divest the assets 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 generic isradipine capsule assets.

The proposed remedy contains provisions to ensure that the divestitures are successful. Abrika's isradipine product is manufactured for Abrika by a third-party manufacturer. As part of the divestiture, Abrika will transfer its supply arrangement to Cobalt. Actavis and Abrika will transfer all confidential business information related to Abrika's isradipine product to Cobalt. Finally, Actavis and Abrika will provide technical assistance to Cobalt to allow it to manufacture isradipine in substantially the same manner and quality employed or achieved by Abrika.

The Commission has appointed Denise F. Smart of Smart Consulting Group, LLC as the Interim Monitor to oversee the asset transfer and to ensure Actavis and Abrika's compliance with all of the provisions of the proposed Consent Agreement. Ms. Smart has over twenty years of experience in the pharmaceutical industry. Her experience includes providing consulting services in healthcare business development and regulatory compliance to major pharmaceutical companies, biotechnology companies and medical device companies. 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 Actavis and Abrika 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.