

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

*In the Matter of Endo International plc*

*File No. 151-0137*

*Docket No. C-4539*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Endo International plc (“Endo”) that is designed to remedy the anticompetitive effects resulting from Endo’s acquisition of Par Pharmaceutical Holdings, Inc. (“Par”). Under the terms of the proposed Consent Agreement, Endo is required to divest all of its rights and assets related to generic glycopyrrolate tablets and generic methimazole tablets.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger executed on May 18, 2015, Endo proposes to acquire Par for approximately \$8 billion. The Commission alleges in its Complaint 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 current competition in the markets for generic glycopyrrolate tablets and generic methimazole tablets. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

**I. The Products and Structure of the Markets**

A generic pharmaceutical drug contains the same active ingredient as the brand name product, but typically at a much more affordable price. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, generic suppliers compete only against each other.

The Proposed Acquisition would reduce the number of current suppliers in the markets for generic glycopyrrolate tablets and generic methimazole tablets. Glycopyrrolate tablets are used to reduce secretions in the mouth, throat, airway, and stomach, mitigating the side effects of peptic ulcer medicines. Only three companies— Endo, Par, and Leading Pharma, LLC— currently supply generic glycopyrrolate tablets in the United States. The proposed transaction would result in a combined market share in excess of 63%. Methimazole tablets inhibit the production of excess thyroid hormone. Four companies—Endo, Par, Sandoz, and Heritage

Pharmaceuticals, Inc.—currently supply generic methimazole in the United States. The combined company would supply approximately 67% of the generic methimazole tablet market.

## **II. Entry**

Entry into the two markets described above would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

## **III. Effects**

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Endo and Par in each of these markets. Market participants characterize generic glycopyrrolate tablets and generic methimazole tablets as commodities, and each market as one in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have observed that the price of these generic pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Further, customers generally believe that having at least four suppliers in each generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for generic glycopyrrolate tablets and generic methimazole tablets.

## **IV. The Consent Agreement**

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition in each relevant market by requiring Endo to divest all its rights to generic glycopyrrolate tablets and generic methimazole tablets to Rising Pharmaceuticals. Owned by Aceto Corporation, Rising Pharmaceuticals develops, sells, and distributes generic pharmaceuticals in the United States. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the proposed acquisition consummates.

The Commission’s goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Rising Pharmaceuticals is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Rising Pharmaceuticals and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. Rising Pharmaceuticals will acquire Endo’s glycopyrrolate and methimazole ANDAs and stream of revenue associated with each product. Endo will supply Rising Pharmaceuticals with glycopyrrolate and methimazole tablets for two years while the company transfers manufacturing technology to Rising Pharmaceuticals’ designated

manufacturer. The proposed Consent Agreement also requires Endo to provide transitional services to Rising Pharmaceuticals to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture glycopyrrolate and methimazole tablets in substantially the same manner and quality employed or achieved by Endo, and advice and training from knowledgeable employees of the parties.

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.