

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

***In the Matter of Teva Pharmaceutical Industries Ltd. and Cephalon, Inc.
File No. 111-0166***

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 Cephalon, Inc. (“Cephalon”) that is designed to remedy the anticompetitive effects of Teva’s acquisition of Cephalon. Under the terms of the proposed Consent Agreement, Teva would be required to divest to Par Pharmaceutical, Inc. (“Par”) all of Teva’s rights and assets relating to its generic transmucosal fentanyl citrate lozenges (“fentanyl citrate”) and generic extended release cyclobenzaprine hydrochloride capsules (“cyclobenzaprine hydrochloride”). Teva will also enter into a supply agreement to allow Par to sell generic modafinil tablets (“modafinil”) for a period of at least one year; Par has the option to extend that supply agreement for up to one additional year if it chooses.

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 Asset Purchase Agreement dated May 1, 2011, Teva proposes to acquire Cephalon in a transaction valued at approximately \$6.8 billion (“Proposed Acquisition”). 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 fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the acquisition.

The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of suppliers in each of the relevant markets. In human pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

Transmucosal fentanyl citrate lozenges are a treatment for breakthrough cancer pain originally developed by Cephalon and marketed under the brand name Actiq. Three companies – Teva, Cephalon/Watson Pharmaceuticals, Inc., and Covidien – manufacture and market a generic version of the product for sale in the United States. Teva and Covidien both manufacture their own products while Watson’s product is manufactured and supplied by Cephalon. In 2010, Teva had 43 percent of generic sales, while the Cephalon/Watson product

had 40 percent and Covidien had 17 percent. Therefore, the proposed acquisition combines the two most competitively significant suppliers of generic fentanyl citrate.

Extended release cyclobenzaprine hydrochloride is an extended release version of Flexeril, a muscle relaxant. Cephalon acquired the North American rights to the branded formulation of extended release cyclobenzaprine hydrochloride, called Amrix, which was approved by the Food and Drug Administration (“FDA”) in 2007. No companies currently market a generic version of Amrix, but Teva and Cephalon (through an authorized generic product¹) are two of a limited number of suppliers capable of entering with a generic cyclobenzaprine hydrochloride product in a timely manner.

Modafinil tablets treat excessive sleepiness caused by narcolepsy or shift work disorder. Cephalon markets modafinil tablets under the brand name Provigil, sales of which totaled approximately \$1 billion in 2010. No companies currently market a generic version of Provigil. Teva, Ranbaxy Pharmaceuticals, Inc., Mylan Pharmaceutical Inc., and Barr Laboratories, Inc. (now owned by Teva) each filed applications seeking FDA approval to market generic Provigil before expiration of Cephalon’s patent. They all filed on the first day that the FDA would accept such an application, making them all eligible for the 180-day marketing exclusivity period provided under the Hatch-Waxman Act.² Subsequently, each of the companies agreed with Cephalon to refrain from marketing generic Provigil until April 2012. Cephalon (through an authorized generic product) and Teva are two of a limited number of suppliers best-positioned to enter with a generic modafinil product during the upcoming Hatch-Waxman exclusivity period for sales of generic modafinil.

Entry

Entry into the markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes at least two years. And even companies for whom the FDA approval process is well underway face other regulatory barriers, including Hatch-Waxman regulatory exclusivity and pending patent litigation, that limit their ability to enter these markets in a timely manner.

¹ Authorized generic products are manufactured by branded pharmaceutical companies and marketed and sold under a non-brand label at generic prices.

² Under the Hatch-Waxman Act, if a generic company plans to launch a generic version of a pharmaceutical product before the patents covering the branded product expire it must certify that its product does not infringe the branded company’s patents or that the branded company’s patents are invalid. The certification usually results in patent litigation. If the generic company successfully challenges the patents held by the branded company, the generic company may be eligible to receive a 180-day period of market exclusivity for its generic product.

Effects

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil. In pharmaceuticals markets with generic competition, price generally decreases as the second, third, fourth, and even fifth competitors enter. Although generic versions of cyclobenzaprine hydrochloride and modafinil are not yet available in the United States, the FDA approval process provides information about the timeliness and likeliness of entry by generic products. In addition, substantial experience and empirical evidence of the impact of multiple generic suppliers on prices for other drugs provide a strong basis to draw conclusions about the likely effects of the Proposed Acquisition in the markets for these products. Moreover, for a drug with high dollar sales such as Provigil, the impact from a reduction of competition during the 180-day exclusivity period alone is substantial. The Proposed Acquisition, by reducing an already limited number of competitors or potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets by requiring Teva to divest certain rights and assets related to generic fentanyl citrate and generic cyclobenzaprine hydrochloride to a Commission-approved acquirer no later than ten days after the acquisition. In addition, to remedy the consolidation of marketers of generic modafinil during the exclusivity period, the Consent Agreement requires Teva to enter into a supply agreement to provide a Commission-approved acquirer with generic modafinil tablets to sell in the United States for at least one year. 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.

The proposed Consent Agreement remedies the competitive concerns the acquisition raises by requiring Teva to divest its generic fentanyl citrate and generic cyclobenzaprine hydrochloride to Par, which will purchase all rights currently held by Teva. In addition, Teva will supply Par with at least a one-year supply of modafinil tablets. Par has the option to extend the modafinil supply agreement for an additional year. Par is a New Jersey-based generic pharmaceutical company with 115 active products and an active product development pipeline. With its experience in generic markets, Par is expected to replicate the competition that would otherwise be lost with the Proposed Acquisition.

If the Commission determines that Par is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale to Par and divest the products, within six months of the date the Order becomes final, to a Commission-approved acquirer. In that circumstance, the Commission may appoint a trustee to divest the products if Teva fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Teva to take all action to maintain the economic viability, marketability, and competitiveness of the products until such time as they are transferred to a Commission-approved acquirer. Teva must transfer the manufacturing technology for the fentanyl citrate and cyclobenzaprine hydrochloride products to Par and must supply Par with fentanyl citrate and cyclobenzaprine hydrochloride products during the transition period.

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.