

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Cephalon, Inc. and Cima Labs, Inc., which is designed to remedy the anticompetitive effects of the acquisition of Cima by Cephalon. Under the terms of the proposed Consent Agreement, Cephalon would be required to grant to a third party company, a fully paid-up, irrevocable license to make and sell a generic equivalent of its breakthrough cancer pain (“BTCP”) drug Actiq in the United States.

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 or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger dated November 3, 2003, between Cephalon and Cima, Cephalon proposes to acquire 100 percent of the issued and outstanding shares of Cima in a stock-for-stock transaction valued at approximately \$515 million. Cephalon also intends to pay consideration such that each issued and outstanding share of Cima common stock will be converted into the right to receive \$34.00 in cash. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would constitute a violation of 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, in the market for prescription drug products indicated for the treatment of BTCP. The proposed Consent Agreement will remedy the alleged violations by replacing the lost potential competition that would result from the merger in this market.

Drugs for the treatment of BTCP help to reduce or eliminate the spikes of intense pain experienced by patients receiving opioid therapy for their chronic pain. By providing a faster onset of pain relief than short-acting oral opioids, BTCP products allow patients to be more active. Because many patients with BTCP are not in hospitals, BTCP products are self-administered and produced in a convenient and portable dosage form. These characteristics of BTCP medications provide terminally ill cancer patients a significant improvement to the quality of their lives. Annual sales of BTCP drugs total more than \$200 million in the United States, and the market is growing rapidly.

The U.S. market for drugs to treat BTCP is a monopoly. Cephalon markets Actiq, the only product currently indicated for the treatment of BTCP on the market. Actiq is a fentanyl-containing, berry-flavored lollipop. Cephalon is also developing a sugar free formulation of Actiq which it expects to launch in 2005. Cima is in Phase III of clinical development of its OraVescent fentanyl (“OVF”) product, which is a fast-dissolving, effervescent, sugar-free fentanyl tablet. Cima intends to seek approval from the Food and Drug Administration (“FDA”) by the end of 2004 or in the first quarter of 2005. OVF is expected to enter the U.S. market in 2006 or 2007 and is the product best-positioned to enter the U.S. market and compete with Cephalon’s Actiq.

Both branded and generic entry into the market for BTCP products is difficult, time consuming, and costly. Cima is the firm best positioned to enter the market. Other firms that have undertaken efforts to develop BTCP products are well behind Cima. In fact, entry in the BTCP market by any other branded or generic firm is not expected to occur until at least 2008. Both generic and branded entry is delayed by numerous barriers, including intellectual property, regulatory, technological, manufacturing, and marketing. Entry, therefore, would not be likely, timely, or sufficient to counteract the anticompetitive effects of the acquisition.

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for BTCP products by eliminating potential competition between Cephalon and Cima. With only one firm currently marketing a BTCP drug to customers in this market (Cephalon), the entry of Cima likely would increase competition and reduce prices for drugs indicated for the treatment of BTCP. Accordingly, allowing Cephalon to control both Cima's product and its own potentially competing product would reduce the number of rivals in the future from two to one and likely force customers to pay higher prices for their BTCP drugs. Moreover, Cephalon's ownership of both products will allow it to undermine generic entry by shifting patients to the patent-protected OVF product prior to generic launch, depriving consumers of the full benefits of generic competition.

The proposed Consent Agreement therefore requires Cephalon to grant a license and transfer all of its technological know-how and intellectual property related to Actiq ("Actiq license assets") to an upfront buyer no later than ten days after the acquisition is consummated. Cephalon has selected Barr Laboratories, Inc. ("Barr") as the upfront buyer. Barr is a reputable generic manufacturer and is well-positioned to manufacture a generic version of Actiq. If the Commission determines that Barr is not an acceptable purchaser, or if the manner of the grant, license, delivery or conveyance is not acceptable, Cephalon and Cima must rescind the transaction with Barr and grant, license, deliver or otherwise convey the Actiq license assets to a Commission-approved buyer not later than six months from the date the Order becomes final. Should they fail to do so, the Commission may appoint a trustee to divest the Actiq license assets.

The proposed remedy contains several provisions designed to ensure the successful and timely development of OVF, sugar-free Actiq, and generic Actiq. Cephalon must transfer all of its technological know how and intellectual property related to both the sugar and sugar free formulations of Actiq to Barr immediately in accordance with the terms of the Cephalon/Barr License and Supply Agreement. In the event that Barr is not able to manufacture an FDA-approved generic version of Actiq by the date the licenses take effect, the Order requires Cephalon to supply Barr with Actiq to be marketed as a generic. The Order also contains date certain provisions that provide incentives for Cephalon not to delay the development and launch of OVF or sugar-free Actiq. The licenses for the marketing rights for sugar and sugar-free Actiq are triggered by dates certain. These dates certain triggers provide Cephalon with a strong incentive to launch OVF as soon as possible or risk Barr's launch of generic Actiq even before Cephalon's OVF. Further, the Order contains provisions that require Cephalon to timely develop the sugar free formulation by a date certain, or if it fails to do so, to license Barr five

months earlier. With the licenses and technology transfer provided by Cephalon, Barr will be able to compete aggressively in the BTCP market against Actiq. The proposed remedy also prohibits Cephalon from making certain regulatory filings that would delay FDA approval of Barr's generic Actiq. These provisions ensure that Barr will be in a position to launch a generic version of Actiq no later than OVF launch, eliminating the anticompetitive effects of the proposed acquisition and providing patients with earlier access to a lower priced generic product.

Normally a generic remedy would not be sufficient to solve the anticompetitive problems raised by a merger of two branded pharmaceutical competitors because it does not replace the lost promotion and innovation competition between branded companies. In this case, the evidence showed that there is not likely to be any further innovation competition between Cephalon and Cima because, among other things, Actiq is near the end of its patent life. Moreover, Actiq and OVF are both formulations of fentanyl, a readily-available, non-patented active ingredient. The facts showed that an important anticompetitive effect of the merger was to defeat generic competition. The evidence in this case also suggests that, regardless of the merger, Cephalon will no longer promote the sugar-based Actiq formulation after OVF's launch. Finally, any lost brand-to-brand price competition which would have occurred between Cephalon and Cima is more than restored by the early entry of lower priced generic versions of sugar and sugar-free Actiq. As a result, the generic remedy replaces the lost price competition that likely would have occurred. The proposed remedy would bring significant benefits to patients and would reverse the anticompetitive effects of the proposed acquisition.

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 Consent Agreement or to modify its terms in any way.