

Parties: Hamburg-Sud, A.P. Moller-Maersk A/S, MSC Mediterranean Shipping Company S.A., CMA CGM, S.A., and Hapag-Lloyd AG.

Filing Parties: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street, NW; Suite 1100; Washington, DC 20006-4007.

Synopsis: The Agreement authorizes Hamburg-Sud, Moller-Maersk, Hapag, Lloyd and CMA CGM to charter space to Med Shipping in the trade between U.S. West Coast ports and ports in Australia, and New Zealand.

Agreement No.: 012140.

Title: CSAV/Siem Turkey Space Charter Agreement.

Parties: Compania Sud Americana de Vapores, S.A. and Siem Car Carriers (Pacific) AS.

Filing Party: Walter H. Lion Esq.; McLaughlin & Stern, LLP; 260 Madison Avenue, New York NY 10016.

Synopsis: The agreement permits CSAV and Siem to cross charter space for the movement of motorized vehicles in the trade from Turkey to the U.S. East Coast.

Agreement No.: 012141.

Title: COSCON and WHL Transpacific Vessel Sharing and Slot Allocation Agreement.

Parties: COSCO Container Lines Company Limited, and Wan Hai Lines (Singapore) Ptd. Ltd.

Filing Parties: Susannah Keagle, Esq.; Nixon Peabody LLP; 555 West 5th Street, 46th Floor; Los Angeles, CA 90013-1025.

Synopsis: The agreement authorizes the parties to operate six vessels and exchange slots in the trades between Vietnam, China, and the United States.

Agreement No.: 201165-001.

Title: Marine Terminal Lease and Operating Agreement.

Parties: Broward County, Saw Grass Transport, Inc., and Dole Fresh Fruit Company

Filing Party: Candace J. McCann; Broward County Board of County Commissioners; Office of the County Attorney; 1850 Eller Drive, Suite 502; Fort Lauderdale, FL 33316.

Synopsis: The amendment revises the legal description of the demised premises and provides for the reassignment of the lease and operating agreement to Dole.

By Order of the Federal Maritime Commission.

Dated: October 14, 2011.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2011-27055 Filed 10-18-11; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 14, 2011.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Midwest Bancshares, Inc.*, to become a bank holding company by acquiring 100 percent of Security State Bank, both of Tyndall, South Dakota, and Dakota Heritage State Bank, Chancellor, South Dakota. Applicant also applied to acquire control of Chancellor Insurance Agency, LLC, Chancellor, South Dakota, and thereby engage in the sale of insurance in a town of less than 5,000, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, October 14, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011-27032 Filed 10-18-11; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL TRADE COMMISSION

[File No. 111 0166]

Teva Pharmaceutical Industries Ltd. and Cephalon, Inc.; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 7, 2011.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Teva Cephalon, File No. 111 0166” on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/tevacephalonconsent>, by following the instructions on the Web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202-326-3085), FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for October 7, 2011), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>. A paper copy can be obtained from the FTC Public Reference

Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 2, 2011. Write “Teva Cephalon, File No. 111 0166” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtml>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,” as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a

result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/tevacephalonconsent> by following the instructions on the Web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you file your comment on paper, write “Teva Cephalon, File No. 111 0166” on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 7, 2011. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Order To Aid Public Comment

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

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

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.

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 likelihood 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.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2011-26970 Filed 10-18-11; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

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.