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 product [1]) 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 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.

By direction of the Commission.

Donald S. Clark,

Secretary.

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

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[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.

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:

Marija Manojlovic, University of Pittsburgh: Based on an inquiry conducted and written admission obtained by the University of Pittsburgh (UP) and additional analysis conducted by ORI in its oversight review, ORI found that Ms. Marija Manojlovic, former graduate student, Department of Chemistry, UP, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant P50 GM067082, National Cancer Institute (NCI), NIH, grant P01 CA078039, National Institute of Mental Health (NIMH), NIH, grant U54 MH074411, and National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI033506.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating the synthesis and spectral data that were included in one (1) poster presentation and in one (1) pre-submission draft of a paper to be submitted for publication.

Specifically, ORI found that the Respondent knowingly falsified and fabricated the synthesis and characterization, largely in the form of manipulated 1H- and 13C–NMR spectral data, for five intermediate steps and the final product, 9-desmethylpleurotin, and presented these false results in a poster, ''Efforts Towards the Total Synthesis of Pleurotin,'' presented at the 2011 National Organic Symposium, and in a manuscript, ''Total Synthesis of 9-desmethylpleurotin,'' prepared for submission to *Angewandte Chemie International Edition.*

Ms. Manojlovic has voluntarily agreed for a period of three (3) years, beginning on September 26, 2011:

(1) To have her U.S. Public Health Service (PHS)-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, she shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) That any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which she is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) To exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011–27022 Filed 10–18–11; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From Oak Ridge National Laboratory (X–10), Oak Ridge, TN, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from Oak Ridge National Laboratory (X–10), Oak Ridge, Tennessee, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Oak Ridge National Laboratory (X–10)

Location: Oak Ridge, Tennessee.

Job Titles and/or Job Duties: All contractor employees, subcontractor employees, and AEC employees who were monitored or should have been monitored for any of the various radionuclides and fission products present at the X–10 plant.

Period of Employment: January 1, 1943 through December 31, 1952.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by e-mail to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011–27035 Filed 10–18–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Senior Executive Service Performance Review Board Membership

The Agency for Healthcare Research and Quality (AHRQ) announces the appointment of members to the AHRQ Senior Executive Service (SES) Performance Review Board (PRB). This action is being taken in accordance with 5 U.S.C. 4314(c)(4), which requires notice of appointment of members to performance review boards to be published in the **Federal Register.**

Members of the PRB are appointed in a manner that will ensure consistency, stability and objectivity in the SES performance appraisals. The function of the PRB is to make recommendations to the Director, AHRQ, relating to the performance of senior executives in the Agency.

The following persons will serve on the AHRQ SES Performance Review Board:

Irene Fraser, Stephen B. Cohen, William Munier, David Meyers, Michael Fitzmaurice, Phyllis Zucker, Mark Handelman, Jean Slutsky.

For further information about the AHRQ Performance Review Board, contact Ms. Alison Reinheimer, Office of Performance, Accountability, Resources, and Technology, Agency for Healthcare Research and Quality, 540 Gaither Road, Suite 4012, Rockville, Maryland 20850.

Dated: October 2, 2011.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 2011–26965 Filed 10–18–11; 8:45 am]

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