Commission may challenge an invitation to collude under Section 5 of the FTC Act even where the conduct did not result in competitive harm.

Corporations have many obvious and important reasons for discussing business strategies and financial results with shareholders, securities analysts, and others. For this reason, the Commission is extremely sensitive to the fact that antitrust intervention involving a corporation's public communications must take great care not to unduly chill legitimate speech.[11]

In this case, the public statements made by Valassis went far beyond a legitimate business disclosure and presented substantial danger of competitive harm. The Commission's complaint alleges that Valassis made a strategic decision to use and did use its analyst call to communicate to News America information that was essential for News America to understand how Valassis proposed to divide up the market and how it proposed to transition from competition to coordination. For example, Valassis specified how it proposed to split the business of those customers it shared with News America and explained what its pricing would be with regard to pending bids to four News America customers. Valassis historically had not provided information of this type to the securities community, analysts had no need for the information and did not report it, and Valassis had no legitimate business justification to disclose the information. Valassis would not have disclosed the detailed information except in the expectation that News America would be monitoring the call and except for the purpose of conveying its proposal to News America.

III. The Proposed Consent Order

Valassis has signed a consent agreement containing the proposed consent order. The proposed consent order enjoins Valassis from inviting collusion and from actually entering into or implementing a collusive scheme.

More specifically, Valassis would be enjoined from inviting an FSI competitor to divide markets, to allocate customers, or to fix prices. The proposed consent order also prohibits Valassis from entering into, participating in, implementing, or otherwise facilitating an agreement with any FSI competitor to divide markets, to allocate customers, or to fix prices.

The proposed order would not interfere with Valassis' efforts to negotiate prices with prospective customers, and it would permit Valassis to provide investors with considerable information about company strategy. The proposed order also includes a safe harbor provision permitting Valassis to communicate publicly any information the public disclosure of which is required by the Federal securities laws.

The proposed order will expire in 20 years.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E6–3965 Filed 3–17–06; 8:45 am]

BILLING CODE 6750–01–P

[11] For example, the Commission would likely not interfere with a public communication that is required by the securities laws. Here, the Commission has been cited to no other instance where a corporation disclosed publicly in securities filings or other fora the detailed descriptions of its future pricing plans and business strategies alleged in this complaint.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0251]

Determination of Regulatory Review Period for Purposes of Patent Extension; MYCAMINE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYCAMINE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to*http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MYCAMINE (micafungin sodium). MYCAMINE is indicated for treatment of patients with esophageal candidiasis and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MYCAMINE (U.S. Patent No. 5,376,634) from Astellas Pharma, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MYCAMINE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MYCAMINE is 2,546 days. Of this time, 1,493 days occurred during the testing phase of the regulatory review period, while 1,053 days occurred during the

approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: March 29, 1998. The applicant claims February 26, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 29, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for MYCAMINE (NDA 21–506) was initially submitted on April 29, 2002.

3. *The date the application was approved*: March 16, 2005. FDA has verified the applicant's claim that NDA 21–506 was approved on March 16, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,814 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination byMay 19, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 18, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions are to be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–3956 Filed 3–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8001]

Memorandum of Understanding Between the United States Food and Drug Administration, the National Cancer Institute, and the Centers for Medicare and Medicaid Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Memorandum of Understanding (MOU) is to set forth an agreement between the Food and Drug Administration (FDA), the National Cancer Institute (NCI), and the Centers for Medicare and Medicaid Services (CMS) to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goal of improving the clinical utility of biomarker technologies as diagnostic and assessment tools that facilitate the development of safer and more effective cancer therapies. This collaboration among FDA, NCI, and CMS shall be known as the Oncology Biomarker Qualification Initiative.

DATES: The agreement became effective January 23, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane (HF–1), Rockville, MD 20857, 301–827–7861, FAX: 301–443–9718.

For NCI: Gregory J. Downing, Office of Technology and Industrial Relations, Office of the Director, National Cancer Institute, 31 Center Dr., MSC 2580—rm. 10A52, Bethesda, MD 20892, 301–496–1550, FAX: 301–496–7807.

For CMS: Peter Bach, Centers for Medicare and Medicaid Services, 20 Independence Ave., SW. (rm. 314G), Washington, DC 20201, 202–205–5610, FAX: 202–690–6262.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S