UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Office of the Director

May 9, 2011

Joseph J. Simons
Paul, Weiss, Rifkind, Wharton & Garrison LLP
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Washington, D.C. 20006

E. Anthony Figg
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Dear Mr. Simons and Mr. Figg:

As you know, the Federal Trade Commission's Bureau of Competition has been investigating whether Synthon Holding B.V. violated one of the filing requirements contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA" or "Act").[1] The Act requires that brand name drug companies and generic drug applicants file certain agreements with the Federal Trade Commission and the U.S. Department of Justice within 10 business days of their execution. The failure to timely file may result in a civil penalty of $11,000 for each day that a required filing has not been made. The Bureau of Competition believes that Synthon's failure to file an agreement with Sanofi-Aventis violated the Act, and therefore Synthon could be subject to a civil penalty enforcement action.

In light of all the circumstances, however, the Bureau of Competition has decided not to recommend that the Commission take enforcement action. Instead, to help ensure future compliance with the Act, the Bureau believes that the pharmaceutical industry would benefit from public guidance about the scope of the MMA filing requirement. Thus, we take this opportunity to address various issues concerning the types of agreements that are subject to the MMA filing requirement. This letter discusses the bases for our conclusions that the agreement in question triggered the filing requirement. The Bureau expects Synthon to consider the contents of this letter in connection with future agreements that may be subject to the MMA.

The MMA Filing Requirement and the Commission's Authority to Seek Civil Penalties

The MMA requires the filing of certain types of agreements between a brand name drug company and a generic drug applicant that has submitted an Abbreviated New Drug Application ("ANDA") containing a Paragraph IV certification (that is, a certification that a patent asserted

[1] Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2461, notes on 21 U.S.C. § 355.

to cover the branded drug product is invalid or not infringed). Section 1112(a)(2) of the Act specifies that such an agreement must be filed if it concerns:

> (A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA involved;
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> (B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or
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> (C) the Hatch-Waxman 180-day exclusivity period as it applies to an ANDA based on the same brand name drug.

Companies must also file the text or a written description of any agreements between them that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required to be filed under the provisions set forth above. MMA § 1112(c)(2).

The only exclusion from the Act's filing requirement is an exception for agreements that solely concern: (A) purchase orders for raw material supplies; (B) equipment and facility contracts; (C) employment or consulting contracts; or (D) packaging and labeling contracts. MMA § 1112(c)(1).

Parties must file their agreements within 10 business days of execution. MMA § 1113. The failure to file may result in an action for civil penalties and other relief in a United States district court by the Commission or the Department of Justice. The penalty may be up to $11,000 for each day a party is in violation of the Act's notification requirement.

The MMA Required Filing of the Sanofi-Synthon Agreement[2]

The agreement at issue is a joint motion and stipulated order seeking a stay of Sanofi's Hatch-Waxman patent infringement suit against Synthon during the pendency of the U.S. Patent and Trademark Office's *inter partes* reexamination of the Ambien CR patent. Under the terms of the stipulated order, Synthon agreed that during the pendency of the stay it would provide Sanofi with 120-days notice of its intention to begin marketing a generic Ambien CR.

On its face, the joint stipulation falls within the MMA's filing requirement: (1) it is an agreement between a brand name drug company and a generic applicant that has submitted a Paragraph IV ANDA; and (2) the agreement concerns the marketing of the ANDA product.

First, the joint stipulation is an "agreement" within the meaning of the MMA, regardless of whether its terms had binding effect without court action. The parties agreed on the terms to propose to the court. Nothing in the MMA suggests that such an agreement is exempt from the statute.

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[2] The agreement discussed in this letter is contained in a public court filing and thus the terms of the agreement are publicly available.

Second, nothing in the statute requires that the elements of a legally binding contract must be satisfied to trigger the filing requirement. Congress used the term "contract" in other parts of the MMA, but used the term "agreement" in Section 1112, a word whose customary meaning is merely something that two parties consent to. Thus, the language of the Act forecloses an argument that a joint stipulation need not be filed absent an exchange of consideration.

Finally, the MMA required the filing of the joint stipulation even if the prior notice obligation had no actual effect on Synthon's ability to market its ANDA product. The language of the statute makes it clear that the MMA filing requirement is triggered by an agreement "regarding" the manufacture, marketing, or sale of the ANDA product. The requirement is not limited to agreements that actually restrict such marketing. Nor does the MMA exempt agreements that the parties believe will have no effect on the sale of the generic drug. The 120-day notice requirement implicates the marketing or sale of generic Ambien CR because of its potential to impede Synthon's ability to launch its ANDA product. This provision therefore triggers the filing requirement, regardless of its actual or anticipated effect.

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In sum, companies should look to the language of the statute first and foremost. Thus, it should be clear that the fact that agreements are in publicly available court filings does not alter a party's filing obligation. Congress did not exempt public agreements from the MMA's filing requirement. The MMA was designed to ensure that the antitrust agencies will be afforded an early opportunity to review agreements that may affect the sale of generic drugs. It would be unrealistic to expect the Commission to monitor all pending Hatch-Waxman patent litigation.

We also note that the MMA's filing requirement is not burdensome. Unlike the Hart-Scott-Rodino ("HSR") premerger filing regime, the MMA imposes no filing fees, and parties are not required to file data or information beyond the relevant agreements themselves. In case of doubt about whether filing is required, companies can contact Commission staff for guidance.

Nevertheless, the Bureau has determined not to recommend that the Commission initiate an enforcement proceeding in this matter. The failure to file does not appear to have been a deliberate effort to evade the requirements of the Act, no party appears to have benefitted from the failure to file, and guidance to the industry in the form of this letter may serve an enforcement purpose of its own. This approach is consistent with the way the Bureau often deals with comparable first-time violations of filing requirements under the HSR Act.

Because the Bureau has determined not to recommend that the Commission take any further action in this matter, the investigation has been closed pursuant to authority delegated by

the Commission. The decision to close the investigation should not be construed as a determination that no violation occurred. The Commission reserves the right to take such further action as the public interest may require.[3]

Sincerely,

Richard A. Feinstein
Director

[3] The Commission is placing this letter on the public record, in part, to serve as a reminder to industry members of their filing obligations under the MMA. We will consider enforcement recommendations, including appropriate penalties, in the future when the MMA filing requirements have not been met.