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

Bureau of Competition
Office of the Director

May 9, 2011

Helene D. Jaffe
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767 Fifth Avenue
New York, NY 10153

Dear Ms. Jaffe:

As you know, the Federal Trade Commission's Bureau of Competition has been investigating whether Sanofi-Aventis 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 Sanofi's failure to file two agreements – one with Watson Pharmaceuticals/Watson Laboratories and another with Synthon Holding B.V. – violated the Act, and therefore Sanofi 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 agreements in question triggered the filing requirement. The Bureau expects Sanofi 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 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:

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

(A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(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-Watson Agreement[2]

One of the agreements at issue is a joint stipulation that Sanofi and Watson submitted to a court when seeking dismissal of a pending Hatch-Waxman patent infringement case concerning Watson's ANDA for a generic version of Ambien CR. In pertinent part, the joint stipulation:

- recites that Watson converted its Paragraph IV certification for generic Ambien CR to a Paragraph III certification, that is, it is no longer seeking FDA approval to market any product under its ANDA prior to expiration of the relevant patent; and

- provides that if Watson converts its Paragraph III certification back to Paragraph IV, it will provide notice to Sanofi and, if Sanofi files a patent infringement suit within 45 days of receiving such notice, agrees that Sanofi is entitled to a new 30-month stay of FDA approval of Watson's ANDA.

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

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[2] Both of the agreements discussed in this letter are contained in public court filings and thus the contents of the agreements are publicly available.

Paragraph IV ANDA; and (2) the agreement concerns the marketing of the ANDA product. We note in particular:

First, the filing requirement applies notwithstanding Watson's conversion to a Paragraph III certification. Section 1112 applies where the generic "has submitted" an ANDA containing a Paragraph IV certification. Unlike other provisions in the MMA, Section 1112 does not require that the generic applicant maintain an active Paragraph IV ANDA.[3]

The language of the statute and its use of the present perfect tense, "has submitted," does not limit Section 1112's application to generic applicants that maintain their Paragraph IV certification.[4] Indeed, such a limitation would create a substantial loophole in the statute: It would enable a generic applicant to evade the filing requirement simply by converting its Paragraph IV certification before entering into an agreement with the brand name drug firm. Any suggestion that Congress intended such a result cannot be squared with either the language or the underlying policy goals of the statute. Had Congress so intended, it could easily have drafted the legislation to accomplish such a limitation. *See* note 3 *supra*.

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.[5]

Third, the joint stipulation is an agreement "regarding the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted." MMA § 1112(a)(2)(B). That is the case notwithstanding that the stipulation was filed pursuant to Federal Rule of Civil

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[3] *See* MMA § 1102(a)(1) (defining a "first applicant" in part as an ANDA filer who "lawfully maintains" an application with a Paragraph IV certification), codified at 21 U.S.C. § 505(j)(B)(iv)(II)(bb); MMA § 1102(a)(2) (defining amendment of Paragraph IV certification as a "forfeiture event," causing a first applicant to lose its claim to the 180-day exclusivity period).

[4] A contention that the present perfect tense is not used to express an action that has been completed is incorrect. *See Barrett v. United States*, 423 U.S. 212, 216-17 (1976) (finding a statute requiring that a firearm "has been shipped or transported" in interstate commerce was applicable because "the interstate commerce reference is in the present perfect tense, denoting an act that has been completed."); *see also* Robert A. Farrell, *Why Grammar Matters: Conjugating Verbs in Modern Legal Opinions*, 40 Loy. U. Chi. L.J. 1, 19 (2008) ("The present perfect tense refers to action already completed or continuing in the present, e.g., 'John has written the letter' or 'John has lived here for many years.'") (*citing* Andrea A. Lunsford, *The St. Martin's Handbook* 625-31 (5th ed. 2003)).

[5] Moreover, on its face, the joint stipulation appears to involve an exchange of consideration, that is, Watson's promise to provide notice to Sanofi and to submit to application of the 30-month stay of FDA approval was required to obtain Sanofi's agreement to the stipulation.

Procedure 41(a) to secure a dismissal – a dismissal that was necessitated by Watson's ANDA conversion, which deprived the court of subject mater jurisdiction. We note that either party could have unilaterally advised the court of Watson's ANDA conversion and moved to dismiss the case. No joint stipulation was required to secure dismissal. And even where a joint stipulation is required to secure the action the parties desire, that fact does not preclude the existence of an agreement between the litigants concerning the sale of an ANDA product (which triggers a filing obligation under the MMA). In any event, the stipulation here goes beyond a simple agreement to seek dismissal of the case. Watson's agreement provided for notice to Sanofi and included terms regarding the application of the 30-month stay of FDA approval. These provisions concern the sale of Watson's ANDA product and so are covered by the MMA, whether or not Watson would be subject to those requirements in the absence of the stipulation. Nothing in the MMA requires that the agreement have an actual effect on the sale of the generic product.

The MMA Required Filing of the Sanofi-Synthon Agreement

The other 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.

Here too, the joint stipulation is an "agreement" within the meaning of the MMA, regardless of whether its terms had binding effect without court action and regardless of whether there was an exchange of consideration. 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.

In addition, 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, such as those at issue here, 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.[6]

Sincerely,

Richard A. Feinstein
Director

[6] 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.