Bureau of Competition
Office of the Director

Helene D. Jaffe
Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153

Dear Ms. Jaffe:

UNITED STATES OF AMERICA

FEDERAL TRADE COMMISSION WASHINGTON, D.C. 20580

May 9, 2011

As you know, the Federal Trade Commission's Bureau of Competition has been
investigating whether Sanofi-Aventis violated one ofthe filing requirements contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA" or "Act").' 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

(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

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 ofthe 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

3 See MMA § 1102(a)(I) (defining a "first applicant" in part as was

."); (See)Tj EMC ET BT /T1_2 1 Tf3 the 3 200S)(nt" "TTd the)Tj E /T1_0 1 T2j 0.015 Tc 11.5 0 0 179 94 18Tc424.49pres (absent)T23.02808.5 3.836 0p (f/Sus (of)Tj40.0233 1Tc 1.47 0t (d d (to)T0 6.023 T4010.0106 referTd (is)T1 4uf312.58c 1.47 0to3 113.26 0.027 Tc4918.72189e)Tj cT BT /T1_0 1164uf312.77 1.816 0al eadyd (is)Tj9 .03308.983.836 0complet (filed)T222.0284 /910.0106 ord (to)Tj40.0073 18c 1.47 0conddeudefining)Tf1 nt" ciddefiningT BT /T1_0 1 T224uf31 0.oTj 0.06 842 62 160 T124.49And a(ca)Tj2718Tj 3.31Teri11.5A.d (to)T1 ase o to to to thatBDC /T1_0 _2we0.0186 Tc 1 1 . 5 0 0 2 0 0 8 . c 1 2 0 2 T 3 4 3 . . 4 9 R o b e d (c a s e) T j 2 7 1 8 T j 3 . 0 c 1 . 4 7 0 A . d (t o) T 0 9 8 the thatBDC 2/T1_0 -_2wj01.0232 Tc 11.3 0 0 3458610160 T124.9TTd (the)Tj ET BT /Suspect <</Conf 0 >>BDC 2/T1_0 -_2w3 0.015 T1628 11.3 0 365 74 160 T124.49St.cant" to t h a t B D C

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 ofthe 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

120-days

120-days patent.

Sanofi's

120-days C 301.82.22 40 Td (or44T BT /T1_42434 04c78432 -1.2ev 446.52 47 Tm (tm 6738)Tj 0.0292 B89 301.82.22 4if BT /T1_0984 0(the)Tj 0.028447581 301.82.22 4Tndency)Tj415 Tc c 197985 0 0rior9.11 44831_0 1 Tf354fi5 0 11.2 246.12 44331 plimitat

We also note that the MMA's filing requirement is not burdensome. Unlike the Hart-Scott-Rodino ("HSR") premerger filing regime, the