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# Antitrust Alert

## FTC Warns Pharma Industry to File Required Hatch-Waxman Settlements; Urges "Close Consideration" of Advisory Statement

May 13, 2011

On May 10, 2011, the Federal Trade Commission (FTC) sent a strong message to the pharmaceutical industry: File any agreement that might be characterized as a drug patent litigation settlement under the Medicare Modernization Act of 2003 (MMA) or expose yourself to potential FTC enforcement litigation, including civil penalties.

Sanofi-Aventis U.S. LLC, Watson Pharmaceuticals, Inc. and Synthon Holding B.V. jointly agreed to a stipulation staying Paragraph IV Hatch-Waxman patent litigation pending reexamination by the Patent and Trademark Office of a patent concerning the Sanofi-Aventis drug Ambien CR. The companies made no MMA filing. On May 10, the FTC Bureau of Competition notified all three companies that the stipulation was subject to mandatory MMA filing requirements. However, in this instance, the Bureau gave the companies a "free pass" and said no enforcement action would be recommended because there was no deliberate evasion of MMA's requirements, no party benefited from the failure to file and the advisory letters sent to the parties would provide valuable guidance to the industry on the importance of strict adherence to the MMA filing requirements. This was a first-time violation by the companies involved.

## The MMA Filing Requirement

The purpose of the MMA filing requirement is to ensure that the antitrust agencies are afforded an early opportunity to review certain agreements that affect competition between generic and branded drugs. The MMA requires covered agreements to be filed within 10 business days of execution.

Section 1112(a) specifies that, where a generic applicant has filed an FDA Abbreviated New Drug Application with a Paragraph IV certification (claiming that a listed branded drug patent is either invalid or not infringed), the following agreements involving the generic applicant must be filed: (i) agreements with a brand firm relating to the marketing, manufacture or sale of the brand or generic product or (ii) agreements relating to the 180-day exclusivity period as it applies to the generic applicant or another generic applicant based on the same brand name drug.

In addition, Section 1112(c) provides that the parties must also file "any agreements" that are "contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required to be filed" under Sections 1112(a) or (b). For covered agreements not reduced to text, a written description disclosing all of the terms and conditions must be prepared and filed. Failure to file may result in an action in U.S. District Court for civil penalties up to $11,000 for each day a party is in violation of the MMA's filing requirement, as well as other relief.

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## Existing MMA Filing Precedent: *FTC v. Bristol Myers Squibb Company*

In 2009, in the first MMA failure-to-file case ever brought, drug maker Bristol-Myers Squibb Company (BMS) paid $2.1 million—the largest penalty allowed by law—for failing to inform the FTC of a settlement agreement with Apotex, Inc. regarding a potential generic version of the BMS drug Plavix.[1] This penalty was also assessed pursuant to BMS' breach of a separate obligation to file under a 2003 FTC consent order settling FTC charges that BMS had entered into agreements with potential generic drug manufacturers to delay their entry into the market in exchange for payments from BMS.[2] Under the terms of the consent order, BMS was required to submit all future drug settlement agreements to the FTC for review.

The BMS/Apotex agreement that gave rise to the 2009 FTC action involved settlement of patent litigation regarding Apotex's plan to launch a generic version of Plavix. In the settlement, BMS granted Apotex a license to launch its generic version of Plavix, and BMS agreed not to launch its own authorized generic for six months following Apotex's entry into the market, thus giving Apotex a true six-month period of generic exclusivity. As required under the 2003 consent order, BMS sought approval of the Plavix agreement. The FTC objected to several provisions in the settlement, including the authorized generic non-compete clause, and BMS, therefore, withdrew the agreement.

BMS and Apotex then renegotiated the settlement terms. BMS again committed not to enter for six months with an authorized generic, but the BMS commitment was only oral. BMS submitted the new written settlement agreement to the FTC, but without referencing the oral commitment. In its own filing pursuant to the MMA, however, Apotex did reference, in a cover letter, the BMS oral commitment not to launch an authorized generic. Faced with conflicting representations, the FTC requested written certification from BMS that its filed agreement represented the totality of the understandings between the parties. BMS made the requested certification without referencing the oral commitment. Apotex made additional submissions to the FTC that were consistent with its earlier stated position. The FTC then sued BMS for failure to file the complete agreement between the parties, in violation of both the MMA and the earlier consent order, and the Justice Department filed criminal false statement charges against BMS.[3]

While the BMS case involves unusual facts, the proposition for which it stands is clear: The antitrust agencies can—and will—investigate the veracity and completeness of MMA filings and insist upon disclosure of the entire relevant agreement even if all parts of it have not been reduced to writing.

## Conclusion

While the Sanofi-Aventis/Watson/Synthon failure-to-file precipitated no FTC enforcement litigation, future parties involved in similar circumstances may not be so fortunate. The FTC's letters to the parties, prominently displayed on the FTC's Web site, were clearly designed to be a warning to the pharmaceutical industry. Hatch-Waxman patent litigation settlements remain a major FTC antitrust focus despite setbacks in the courts. The FTC can be counted on to aggressively insist upon complete and timely filings of all relevant settlement agreements, whatever form those agreements may take. Parties in doubt as to whether a particular agreement falls within MMA filing requirements should contact counsel who can advise on the rules and, if necessary, consult with FTC staff informally.

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[1] *See* FTC Press Release, March 31, 2009, *available at* http://www.ftc.gov/opa/2009/03/bmsplavix.shtm.

[2] BMS settled FTC charges that it had engaged in a series of anticompetitive acts over a 10-year period to obstruct the entry of low-price generic competition for three of BMS' widely used pharmaceutical products: two anticancer drugs, Taxol and Platinol, and the antianxiety agent BuSpar. *See* FTC Consent Order *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[3] The FTC subsequently referred the matter regarding BMS' certification to the Department of Justice (DOJ) for possible investigation of felony false statements. On May 30, 2007, the DOJ announced that BMS agreed to plead guilty and pay a $1 million criminal fine for lying to the federal government. *See* Bristol-Myers Squibb Pleads Guilty to Lying to the Federal Government About Deal Involving Blood-Thinning Drug, May 30, 2007, *available at* http://www.justice.gov/opa/pr/2007/May/07_at_388.html.

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