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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Clarifying Obligation To Report Drug Patent Agreements

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On May 9, 2011, the Federal Trade Commission's Bureau of Competition notified Sanofi-Aventis U.S. LLC, Watson Pharmaceuticals Inc. and Synthon Holding BV that the companies' failure to inform the FTC and the U.S. Department of Justice about patent agreements concerning Sanofi's insomnia drug, Ambien CR, violated the reporting requirements of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The notifications came in the form of "advisory letters," which purported to clarify the patent agreement filing requirements under the MMA.

While the decision not to initiate enforcement proceedings may reflect the ambiguity of the statute — or the fact that a plain-language reading of the statute appears not to require filing in the circumstances at issue — it is clear that the FTC staff's views will next be manifested through an enforcement action and that agreements relating to generic drugs must be evaluated accordingly.

As discussed more fully below, the advisory letters identify various classes of agreements as ones that the FTC staff says are subject to the MMA's filing requirement:

- Agreements, including ones settling litigation, in which the generic manufacturer converts a Paragraph IV certification to a Paragraph III certification;

- Agreements having no actual effect on the manufacture, marketing or sale of a generic drug but that include provisions (such as prior notice of the generic's conversion of its Paragraph III certification back to a Paragraph IV certification or of an intent to market a generic drug, and an agreement by the generic to an additional 30-month stay in the event a new patent infringement suit is filed) that are "regarding" the manufacture, marketing or sale of the generic drug; and

- Agreements to dismiss a patent infringement action reflected in a joint motion, irrespective of a court's disposition of the motion.

But the rationale behind the advisory letters extends beyond the context presented — to agreements outside of litigation and to ones that are entered into relating to generic drugs for which a Paragraph IV certification has been withdrawn. We discuss below the somewhat technical nature of the issue to put the scope of the FTC staff's advice into context.

Background of the MMA's Reporting Requirements

Under the MMA, brand name and generic drug companies must file drug patent agreements with the FTC within 10 days of the execution of the agreement(s). Failure to do so can result in civil penalties of $11,000 for each day that a required filing is not made.

The reporting requirements of the MMA fall into two categories — agreements between (1) brand

name and generic companies (addressed in Section 1112(a)) and (2) only generic companies (addressed in Section 1112(b)).

Section 1112(a) requires a brand name company and a generic drug company that "has submitted an ANDA [(Abbreviated New Drug Application)]" containing a Paragraph IV certification to file with the FTC and DOJ any "agreement" between them "regarding":

A. The manufacture, marketing or sale of a brand name drug that is listed in the ANDA involved;

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

C. The 180-day period referred to in Section 505(j)(5)(B)(iv) of the Federal Food, Drug and Cosmetic Act (the "FFDCA") as it applies to such ANDA or to any other ANDA based on the same brand name drug.

The agreement must be filed before the date that the generic drug subject to the ANDA is first commercially marketed.
Section 1112(b) addresses generic-generic agreements. It requires that generic companies that have each submitted an ANDA containing a Paragraph IV certification with respect to a listed drug report to the FTC and DOJ any agreement between them related to the 180-day period referred to in Section 505(j)(5)(B)(iv) of the FFDCA. The agreement must be filed before the date that the generic drugs subject to the ANDAs are first commercially marketed.

Section 1112(c) of the MMA additionally requires the filing of any other agreement between two drug companies that, while not specifically described in Sections 1112(a) or (b), is contingent upon, provides a contingent condition for or are otherwise related to the agreements articulated in those subsections.[1]

Section 1112(c) sets forth limited exceptions to the filing requirements in Sections 1112(a) and (b) for agreements that solely concern:

A. Purchase orders for raw materials;

B. Equipment and facility contracts;

C. Employment or consulting contracts; or

D. Packaging and labeling contracts.

The FTC Staff's Advisory Letters to Sanofi and Watson, and Synthon

The FTC staff's advisory letters to Sanofi, Watson and Synthon relate to separate patent agreements Sanofi made with the generic companies Watson and Synthon concerning Sanofi's patented insomnia drug, Ambien CR.

The Sanofi-Watson Letters

Sanofi filed a patent infringement action against Watson relating to Watson's proposed manufacture and sale of a generic version of Ambien CR.

Sanofi and Watson submitted a joint stipulation to the court indicating, inter alia, that (1) Watson converted its Paragraph IV certification to a Paragraph III certification (i.e., no longer seeking FDA approval to market its generic version of Ambien CR before the patent expiration), (2) if Watson ever converted the certification back to a Paragraph IV certification, it would provide Sanofi with notice and (3) if Sanofi filed an infringement suit within 45 days after receiving such notice, Sanofi would be entitled to a new 30-month stay of the FDA's approval of Watson's ANDA.

While the bases for Sanofi's and Watson's failure to report the joint stipulation have not been disclosed, it appears the parties may not have done so because, inter alia, (1) Watson's Paragraph IV certification was converted to a Paragraph III certification, and Section 1112(a)'s reporting requirements are triggered only for a Paragraph IV certification and/or (2) the joint stipulation

between Sanofi and Watson was not anti-competitive and did not directly affect the sale of a generic drug, but merely sought to dismiss the case, thus not triggering a filing requirement for an agreement under Section 1112(a) pertaining to the manufacture, marketing or sale of the brand name/generic drug, or to the 180-day exclusivity period.

The FTC staff disagreed with this reasoning. First, it advised that the joint stipulation is an agreement between a brand name drug company and a generic applicant that submitted a Paragraph IV ANDA. Focusing on the "has submitted an ANDA" language in Section 1112(a), the FTC staff opined that Section 1112 does not require a generic applicant to maintain an active Paragraph IV certification. In other words, Watson's initial Paragraph IV certification was enough to trigger the MMA's reporting requirements for any applicable Section 1112(a) agreement it reached with Sanofi — the fact that Watson later converted its Paragraph IV certification to a Paragraph III certification was irrelevant in the FTC staff's eyes.

Second, the FTC staff advised that the joint stipulation between Sanofi and Watson constituted an agreement under Section 1112(a) regarding the manufacture, marketing or sale of the generic version of Ambien CR. According to the FTC staff, the joint stipulation did not simply seek to dismiss the case. Rather, it included Watson's agreement to provide notice to Sanofi and included terms concerning the application of the 30-month stay of FDA approval.

While these terms may not have had an actual effect on the sale of Watson's generic product, the FTC staff nevertheless advised that the agreement was "regarding" the sale of Watson's ANDA product, and therefore triggered the MMA's reporting requirements. Although the FTC staff ultimately noted that the agreement did not harm consumers or competition, reporting of the agreement was still required by the parties under the MMA.

The Sanofi-Synthon Letters

Sanofi also brought a patent infringement suit against Synthon regarding Ambien CR. In this action, Sanofi and Synthon filed a joint motion and stipulated order that sought a stay of Sanofi's suit against Synthon during the U.S. Patent and Trademark Office's inter partes examination of the Ambien CR patent. In the stipulated order, Synthon agreed that, during the pendency of the stay, it would provide Sanofi with 120-days notice of its intent to first begin marketing a generic version of Ambien CR.

While the bases for Sanofi's and Synthon's failure to report the joint stipulation have not been disclosed, it appears that Sanofi and Synthon may have determined that the joint motion and stipulated order (1) had not yet received court approval and was therefore not yet an "agreement" as articulated under the MMA and/or (2) had no actual affect on Synthon's ability to market a generic version of Ambien CR® and was not anti-competitive. Again, the FTC staff disagreed.

It first noted that the joint motion and stipulated order constituted an agreement between a brand name drug company and a generic applicant that had submitted a Paragraph IV ANDA. The FTC staff opined that, regardless of whether the court granted the joint motion and entered the stipulated order, the documents still evidenced an "agreement" between Sanofi and Synthon as defined under the MMA, because the parties agreed on the terms of the motion and order that they ultimately proposed to the court.

Second, similarly to the Sanofi-Watson agreement, the FTC staff advised that the Sanofi-Synthon joint motion and stipulated order evidenced an agreement under Section 1112(a) regarding the manufacture, marketing or sale of a generic version of Ambien CR. Again, the FTC staff noted that the MMA did not require an actual effect on, or restriction of, Synthon's ability to market or sell its generic product. Rather, any agreement that is simply "regarding" the marketing or sale of a generic product is sufficient to trigger the MMA's reporting requirements.

Because Synthon agreed to provide Sanofi with a 120-day notice period prior to its intent to market a generic Ambien CR product, the FTC staff determined that such agreement fell under Section 1112(a) and should have been reported to the FTC and DOJ. Again, the FTC staff did not deem the agreement anti-competitive, but considered this fact not to affect the parties' reporting obligations under the MMA.

What's Next

Patent agreements remain a hot button issue with the FTC and it is no surprise that the FTC staff evinced an expansive view of the MMA reporting requirements. Nor can one doubt that the FTC is fully prepared next time to make its point through an enforcement action — including against agreements that may fall within the spirit of the FTC staff's rationale if not the four corners of the three advisory letters.

While the advisory letters do not have the force of law, and (among other reasons because they are just staff views) are not technically entitled to deference as constructions of the MMA, one may only ignore them at one's peril. Barring a stomach for dispute, the simple and practical rule may simply be to presume that agreements relating to patented drugs and the sale of generic drugs will be considered subject to disclosure unless analysis gives comfort that neither the letter of the law nor the animating spirit behind the FTC staff's views counsels otherwise. We note especially in this regard that the letters, while issued in the context of agreements resolving litigation, are not limited to that context.

Additionally, the conclusion that the submission of a Paragraph IV certification at any time attaches consequences under the reporting requirements forever would seem to require ongoing diligence in changed circumstances of a type not previously envisioned. A range of agreements, for example involving authorized generics, might thus now for the first time be considered possibly subject to the reporting requirement.

--By David M. Goldstein (pictured), Richard S. Goldstein, Robert P. Reznick and Howard M. Ullman, Orrick Herrington & Sutcliffe LLP

Orrick partners Robert Reznick, David Goldstein and Richard Goldstein, and counsel Howard Ullman are members of the Orrick's antitrust and global competition practice group who focus on the representation and counseling of pharmaceutical and other companies in the life sciences industry. Reznick is resident in Orrick's Washington, D.C., office; David Goldstein and Ullman are resident in Orrick's San Francisco office; and Richard Goldstein is resident in Orrick's New York office.

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[1] To the extent that any agreement described in Sections 1112(a) or (b) is not reduced to writing, Section 1112(c) of the MMA requires each of the parties involved to file a written description of the agreement with the FTC and DOJ that is sufficient to disclose the terms and conditions.