

Is that Everything? Antitrust Filing Obligations for Pharmaceutical Settlement Agreements

By Seth Silber & Matthew Bye

Introduction

In 2003, Congress enacted a requirement that certain pharmaceutical patent settlements be submitted to the Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) for review. This patent settlement filing requirement was enacted to ensure that the FTC, in particular, could obtain notice of agreements that may adversely impact consumer welfare, and also better position the FTC to challenge them under the antitrust laws.

Pharmaceutical firms have had to become familiar with the specific terms of this filing requirement since its enactment. This article discusses why Congress created this notification system, provides a detailed review of its relevant provisions, and then discusses a recent settlement agreement between Bristol-Myers Squibb (“BMS”), a brand-name pharmaceutical company, and Apotex, a generic firm, that, unusually, resulted in a DOJ criminal investigation and BMS guilty plea to felony false statements. The article seeks, in particular, to highlight certain steps that counsel should take to ensure that complete pharmaceutical settlement agreements are filed with the agencies.

The Hatch-Waxman Amendments

Congress passed the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act in 1984 in order to “make available more low cost generic drugs.”¹ These amendments sought to balance two conflicting policy objectives: providing incentives for brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products while simultaneously encouraging generic companies to bring less expensive versions of those drugs to market.²

While the regulatory structure of Hatch-Waxman involves many complex provisions,³ there is one provision that is particularly significant to pharmaceutical patent settlements: the granting of 180 days of marketing exclusivity to the first generic manufacturer to file an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) that certifies that the brand-name company’s patents covering the relevant drug product are either invalid or not infringed by the generic company’s proposed drug.⁴ These filings are typically referred to as Paragraph IV certifications.

Through the 180-day exclusivity period, the Hatch-Waxman amendments sought to provide an increased economic incentive for generic companies to challenge patents on branded products. While the 180-day provision has been successful in facilitating generic drug entry, certain settlements between brand-name and generic drug companies have been alleged to game this provision, resulting in delayed

¹ H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

² *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted).

³ See generally FTC, Study, Generic Drug Entry Prior to Patent Expiration: An FTC Study 3-9 (July 2002), (“*FTC Generic Drug Study*”), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

⁴ 21 U.S.C. § 355(j)(5)(B)(iv).

generic market entry.⁵ To ensure that the FTC, in particular, could review agreements implicating the 180-day exclusivity and challenge any that harm consumer welfare under the antitrust laws, Congress passed a patent settlement filing requirement as part of broader Medicare reform legislation titled “The Medicare Prescription Drug, Improvement, and Modernization Act of 2003” (the “MMA”).⁶ As Senator Leahy noted, the purpose of this requirement was to give the FTC and DOJ “access to information about secret deals between drug companies that keep generic drugs off the market.”⁷

At the time the MMA filing requirement went into effect, the FTC had investigated and brought several enforcement actions based on the theory that a payment from a brand firm to a generic company, in the context of a patent settlement, had likely anticompetitive effects where the payment caused a delay of the generic’s entry into the market.⁸ As a consequence, Congress likely perceived that the FTC possessed sufficient legal authority to continue challenging potentially anticompetitive pharmaceutical settlements, and thereby simply required parties to provide *notice* of such settlements.

Consistent with this notification requirement, the FTC has stated, for example, that it “neither approves nor denies approval to the filed agreements.”⁹ In addition, while parties are required to submit certain types of settlement agreements, they may perform the agreement as soon as it is executed.¹⁰ By contrast, when Congress created a regime for the agencies to review potentially anticompetitive mergers and acquisitions, it included a mandatory waiting period before the parties could close their transaction.¹¹

Following the enactment of the MMA, two appellate court decisions have substantially narrowed, if not completely undermined, the FTC’s theory of anticompetitive harm. Specifically, the Eleventh Circuit reversed the FTC decision in the *Schering-Plough* case, and the Second Circuit’s *Tamoxifen* decision upheld a district court decision finding a settlement lawful despite the presence of a payment from the brand to the generic.¹² Despite these rulings, the FTC continues to review the competitive implications of agreements filed under the MMA.¹³

⁵ *FTC Generic Drug Study* at 57-63.

⁶ Pub. L. No. 108-173, 117 Stat. 2066.

⁷ Drug Competition Act of 2001, S. 754, (Senate, November 18, 2002).

⁹ The Commission had, in particular, issued an Opinion in 2003 finding that “reverse-payment” settlements between Schering-Plough and generic firms Upsher-Smith and American Home Products violated the antitrust laws. *FTC v. Schering-Plough Corp.*, 136 F.T.C. 956 (2003), *rev’d*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

⁹ “Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,” (Question 4), *available at* <http://www.ftc.gov/os/2004/01/050210pharmrulesfaqsection.pdf>.

¹⁰ *Id.* (Question 5: “Can I go forward with the agreement after it has been filed, even if I have not heard from the FTC?” Answer: “Yes. Unlike the merger review process under the Hart-Scott-Rodino Act, there is no waiting period.”).

¹¹ Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a.

¹² *FTC v. Schering-Plough*, 402 F.3d 1056; *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, ___ U.S. ___, 127 S. Ct. 3001 (2007). Following those decisions, there have been legislative proposals that address the permissibility of “reverse-payment” settlements. *See* S. 316, H.R. 1432, and H.R. 1902.

¹³ Most recently, the FTC initiated a district court challenge against Cephalon for entering into allegedly anticompetitive agreements with four generic drug makers. FTC Press Release, *FTC Sues Cephalon, Inc. for*

MMA Filing Requirements

The MMA provides that two types of agreements must be filed with the antitrust agencies within 10 business days of execution:

- Brand-generic agreements. Under Section 1112(a), a filing is required where a generic applicant has submitted a Paragraph IV certification to the FDA and enters into an agreement: (1) with a brand firm relating to the marketing, manufacture, or sale of the brand or generic product; or (2) that relates to the 180-day exclusivity period as it applies to the generic applicant or another generic applicant based on the same brand name drug.¹⁴
- Generic-generic agreements. Under Section 1112(b), agreements between two generic companies must be filed where the generic applicants have submitted Paragraph IV certifications to the FDA and have entered into an agreement that relates to the 180-day exclusivity period.¹⁵

The notification provisions of the MMA are broadly drafted to ensure that parties file the entire agreement with the antitrust agencies. In particular, Section 1112(c)(2) provides that the parties must file “any agreements” that are not described in the two categories noted above, but are “contingent upon, provide a contingent condition for, or are otherwise related” to agreements required to be filed under Sections 1112(a) or (b). In addition, Section 1112(c)(3) states that:

In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection *has not been reduced to text*, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

This provision requiring the filing of oral agreements proved to be pivotal in the BMS settlement with Apotex.

Background on the BMS-Apotex Settlement

In November 2001, Apotex filed an ANDA and a Paragraph IV certification with the FDA seeking approval to sell a generic form of a BMS blood-thinning drug product called Plavix.¹⁶ BMS responded by filing suit against Apotex for infringement of the company’s ‘265 patent, which related to Plavix. In early 2006, BMS and Apotex began to discuss a possible settlement of this litigation that would involve BMS granting Apotex a license to launch its own generic version of Plavix. During negotiations, Apotex insisted, among other things, that BMS agree not to launch an “authorized generic”¹⁷ of Plavix after Apotex entered this market. In March 2006, BMS agreed not to launch an

Unlawfully Blocking Sale of Lower-Cost Generic Versions of Branded Drug Until 2012 (Feb. 13, 2008), available at <http://www.ftc.gov/opa/2008/02/ceph.shtm>.

¹⁴ The FTC has produced a summary of the filing requirement, including information on the modalities of submission, which is available at <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>.

¹⁵ Agreements falling within these two categories are *not* required to be filed if they solely concern purchase orders for raw materials, equipment and facility contracts, employment or consulting contracts, or packaging and labeling contracts. Section 1112(c)(1).

¹⁶ Details regarding the BMS-Apotex negotiations and FTC review of the settlement are set forth in the “Information Statement” submitted by the DOJ in support of the plea agreement ultimately entered into by BMS. This statement is available at <http://www.usdoj.gov/atr/cases/f223800/223808.htm>.

¹⁷ An “authorized generic” is a generic version of a drug product launched by the brand either on its own or through a generic licensee. The launch of such products generally takes sales away from the generic launching its version of

authorized generic for six months following Apotex's entry and the parties thereby finalized a settlement.¹⁸

In addition to the MMA notification provisions, BMS was subject to a prior FTC consent order that required the company to secure the FTC's approval for certain patent settlements with generic firms, including Paragraph IV settlements like the settlement with Apotex.¹⁹ When BMS sought FTC approval of the Plavix agreement, the FTC objected to several provisions in the settlement, including the authorized generic provision, and informed BMS that it would reject the agreement.²⁰

As a consequence, BMS and Apotex began meeting in May 2006 to renegotiate terms, recognizing that the FTC would not approve a revised settlement that contained any restrictions on BMS' ability to launch an authorized generic. At these meetings, a BMS official nonetheless made oral representations to Apotex that caused Apotex to understand that BMS would not launch an authorized generic if the parties were able to reach a revised settlement agreement.²¹ The parties thereby reached a revised agreement, which BMS resubmitted—without reference to the company's oral commitment not to launch an authorized generic—to the FTC for review.²²

Apotex simultaneously filed copies of the agreement pursuant to its obligations under the MMA. In addition to providing the written agreement, Apotex also filed a letter disclosing "certain oral agreements reached between Apotex and [BMS] relating to the Revised Agreement," as required by Section 1112(c) of the MMA. In this letter, Apotex stated that it had reached an oral agreement with BMS whereby BMS would not launch an authorized generic.²³

After receiving Apotex's letter, the FTC requested that BMS provide a written certification confirming that it "ha[d] not made any representation, commitment, or promise to Apotex, whether oral or written, that is not explicitly set forth in the Revised Agreement, including the representation that [BMS] would not launch an authorized generic version of Plavix during Apotex's period of exclusivity." BMS executed this certification and did not disclose any oral agreement or understanding regarding the launch of an authorized generic.²⁴

The DOJ's Criminal Investigation

Although the FTC has the predominant role regarding pharmaceutical antitrust issues, and thus the review of settlement agreements filed under the MMA, the DOJ has sole jurisdiction relating to criminal antitrust matters. Upon receiving the certification from BMS, the FTC referred the matter to the DOJ for possible investigation of felony false statements. The DOJ promptly launched a criminal

the branded product. The FTC is currently studying the competitive implications of authorized generics. Additional information is available at <http://www.ftc.gov/opa/2007/04/fyi07238.shtm>.

¹⁸ *Information Statement* at ¶14.

¹⁹ The prior consent order pertained to BMS's BuSpar product and concerned allegations relating to the improper listing of patents in the FDA's "Orange Book," in addition to a prior patent settlement entered into between BMS and Schein. Information concerning this consent is available at <http://www.ftc.gov/opa/2003/03/bms.shtm>.

²⁰ *Information Statement* at ¶¶ 17-18.

²¹ *Information Statement* at ¶¶ 19-22.

²² *Information Statement* at ¶¶ 23-25.

²³ *Information Statement* at ¶ 26.

²⁴ *Information Statement* at ¶¶ 27-28.

investigation and, among other things, conducted an FBI raid of BMS' office in New York City in July 2006.²⁵

On May 30, 2007, DOJ announced that BMS agreed to plead guilty and pay a \$1 million criminal fine for lying to the federal government.²⁶ The guilty plea resolved two felony false statements counts:

- Count One, which concerned the submission of the agreement to the FTC without reference to the oral terms, stated that BMS knowingly and willfully “failed to disclose certain information . . . which was material to the FTC and, therefore, operated as an incomplete and false statement to the FTC.”
- Count Two, which related to the events surrounding the certification, similarly stated that the certification constituted an “incomplete and false statement” to the FTC.²⁷

In an accompanying press release, the head of DOJ's Antitrust Division, Thomas Barnett, stated that

BMS is charged with both lying to the federal government and with taking steps to conceal its false statement – both serious felonies. The seriousness of the offenses is compounded by the fact that BMS' obstructive conduct occurred in connection with the FTC's review of a proposed patent settlement affecting the cost of a lifesaving drug sold to tens of millions of Americans.²⁸

Conclusion

There are two fundamental lessons that can be drawn from this matter. First, parties must ensure that they have a detailed understanding of the MMA pharmaceutical settlement notification provisions and, if uncertain about the requirements of any particular provision, should contact outside counsel and/or FTC staff to discuss. Notably, Commission staff has made clear that it is “willing to discuss issues with private parties in advance of their filing an agreement.”²⁹

Second, the BMS episode has elevated scrutiny at the FTC regarding the completeness of patent settlement filing submissions. Thus, counsel must ensure that they submit the *entire* terms of any agreement required to be submitted under the MMA (or prior consent agreements), including: (1) all relevant written provisions and “related” agreements under Section 1112(c)(2); and (2) a written description of any oral terms as required under Section 1112(c)(3).

In addition, counsel assisting in the preparation of any filing agreement in these circumstances should take particular care to ensure that there is no ambiguity as to what the parties have agreed and that any oral agreements are accurately captured. Business representatives should, furthermore, be made aware of the criminal consequences of failing to completely and accurately comply with the MMA filing

²⁵ Stephanie Saul, *A Generic Drug Tale, With an Ending Yet to Be Written*, N.Y. Times (Aug. 15, 2006), available at http://www.nytimes.com/2006/08/15/business/worldbusiness/15drug.html?_r=1&oref=slogin.

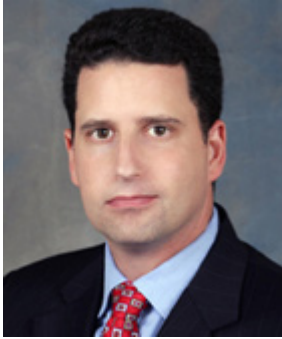
²⁶ DOJ Press Release, *Bristol-Myers Squibb Pleads Guilty to Lying to the Federal Government About Deal Involving Blood-Thinning Drug*, May 30, 2007, available at <http://www.newyork.fbi.gov/dojpressrel/pressrel107/falsestatement053007.htm>.

²⁷ *Id.*; *Information Statement* (Counts I and II), at pp. 8-9.

²⁸ DOJ Press Release, May 30, 2007.

²⁹ MMA Filing FAQ, Question Three.

provisions. To the extent counsel discover any ambiguity as to what the parties have agreed, they should seek to resolve that uncertainty by revisiting negotiations with other parties and reducing these terms to written text.



Seth Silber and Matthew Bye are attorneys in the Washington, D.C. office of Wilson Sonsini Goodrich & Rosati where they focus on antitrust counseling and litigation. Both Seth and Matthew worked at the FTC before joining the firm in 2006. Seth served as an antitrust advisor to Commissioner Jon Leibowitz, and previously was a staff attorney in the FTC's Health Care Division, where he investigated and litigated cases – including Schering-Plough – involving the pharmaceutical industry. Matthew served as an advisor to former Commissioner Orson Swindle, and was a primary author of the FTC's 2004 report "Improving Health Care: A Dose of Competition" and its 2002 report "Generic Drug Entry Prior to Patent Expiration."