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Crime and Patents

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Competition Law Insight
29 July 2008

www.dechert.com

First published in *Competition Law Insight*, 29 July 2008.

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You must be rigorously honest when reporting patent settlement agreements to US antitrust authorities

*by **Jeffrey W Brennan** and **Michael D Farber***

Maintaining patent protection for innovative pharmaceutical treatments and managing the inevitable patent disputes and litigations that arise with successful innovations are among the most important issues facing executives at pharmaceutical companies. Dealing with these issues, particularly in the United States, has become a legal minefield. Recent prosecutions by the US Department of Justice have demonstrated that criminal exposure is perhaps the most damaging of the mines in the field.

In April 2008, a grand jury indicted Andrew Bodnar, a former senior executive of the pharmaceutical manufacturer Bristol-Myers Squibb Company (BMS), for lying to the US Federal Trade Commission (FTC) about a provision in a patent litigation settlement agreement involving the popular brand-name blood-thinning drug, Plavix. This indictment followed a guilty plea by BMS in 2007, in which the company admitted to much of the conduct alleged in the indictment of Mr Bodnar.

These criminal enforcement actions demonstrate that companies and their executives – inside the pharmaceutical industry and outside – must use extraordinary care to be truthful in their representations to the government in civil antitrust investigations. These actions also show that patent settlement agreements can, in some circumstances, also result in criminal exposure if a party's representations to the FTC are perceived to be wilfully inaccurate or incomplete.

For several years, the FTC has closely scrutinised patent settlement agreements between branded and generic pharmaceutical companies for potential adverse effects on competition. Government focus on competition in this sector is by no means limited to the US. When, in January 2008, the European Commission launched an investigation into competition between branded and generic pharmaceutical companies in the European Union, Commissioner Kroes stated: "Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why and, if necessary, take action."

A familiar fact pattern

The *BMS/Bodnar* cases begin with a familiar fact pattern – a patent dispute resulting in litigation in US courts.

A partnership between BMS and Sanofi-Aventis holds an exclusive licence to a patent covering the active ingredient in Plavix, which is a widely-prescribed blood-thinning drug prescribed to reduce heart attacks, strokes or other symptoms of arterial disease. In November 2001, Apotex Corporation, a generic drug manufacturer, filed an abbreviated new drug application (ANDA) with the Food and Drug Administration for approval to manufacture and sell in the US a generic version of Plavix. With the ANDA, Apotex certified that its product did not infringe the Plavix patent or that the patent was invalid. As the first to file an ANDA containing such a certification (known in the trade as a "paragraph IV certification"), Apotex became eligible, once the FDA approved the ANDA for commercial sale, for 180 days of generic marketing exclusivity.

Exclusivity is a feature of the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act (21 USC § 355) (Hatch-Waxman), which, among other things, governs FDA approval of generic drugs, including (where applicable) generic entry prior to branded drug patent expiration. Hatch-Waxman rewards with 180-day exclusivity the "first-filer" of an ANDA containing a paragraph IV certification, to create an incentive for generic firms to be the first to design around drug patents and endure the costs and risks of likely infringement litigation. If exclusivity attaches, then the FDA may not approve later-filed ANDAs until the first-filer's exclusivity period has run. This period frequently begins with the first-filer's initial commercial sale of the approved generic product.

Although Hatch-Waxman provides for this temporary hold on FDA approval of subsequent ANDAs, the statute does not prevent the incumbent brand company from launching a generic version of its branded product during the first-ANDA-filer's 180-day exclusivity period. A brand company's generic version of its own branded drug is known as an "authorised generic."

Shortly after Apotex filed its ANDA, BMS and Sanofi (in March 2002) sued Apotex for patent infringement. Apotex counterclaimed that the patent at issue was invalid. The litigation continued through March 2006, when BMS, Sanofi and Apotex negotiated a settlement agreement.

The initial settlement agreement

Under the settlement agreement, Apotex was granted a licence to manufacture and sell its generic version of Plavix in the US in September 2011 – about two months prior to patent expiration. The licence was exclusive for the first six months. In addition, BMS promised not to launch an authorised generic version of Plavix during that six-month period.

BMS submitted the Apotex settlement agreement to the FTC for approval. It did so because, since 2003, BMS has been subject to an FTC consent order (related to allegations of anticompetitive conduct having nothing to do with Plavix) that requires it, among other things, to obtain FTC approval prior to finalising patent settlement agreements like this one. (FTC prior approval of patent settlements is not otherwise

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required by law.) The agency refused to approve the agreement, however, objecting on competition grounds to the restriction on BMS's ability to market an authorised generic in competition with Apotex for the first 180 days after the latter's entry under the licence. In May 2006, BMS withdrew the agreement from consideration by the FTC.

The second settlement agreement

BMS, Sanofi and Apotex returned to the bargaining table later that May to try again for a settlement. According to the indictment, Mr Bodnar was the only BMS or Sanofi executive who attended negotiations with two executives from Apotex. The indictment alleges that Mr Bodnar "made representations to Apotex to reassure it that BMS would not launch an authorised generic version of Plavix during Apotex's period of exclusivity in the event that the parties reached" a revised settlement agreement. The parties reached such an agreement (with Mr Bodnar signing on behalf of BMS) in late May 2006.

On 30 May 2006, BMS submitted the revised settlement agreement to the FTC. BMS did not disclose the existence of any agreement (oral or otherwise) regarding BMS's future launch or non-launch of an authorised generic.

A few days later, Apotex also filed the revised settlement agreement with the FTC and the Department, which it was required to do under the Medicare Prescription Drug Improvement and Modernization Act 2003 (the MMA) (Pub L No 108-173, 117 Stat 2066). The MMA requires, among other things, notification to the FTC and the Department of certain patent settlement agreements between a brand and an ANDA filer that had made a paragraph IV certification. The MMA requires parties to submit all relevant written provisions and "related" agreements and a written description of any oral terms. Apotex filed not only the written revised settlement agreement, but also a letter in which it reported an oral agreement with BMS, pursuant to which BMS would not launch an authorised generic during the period of Apotex's exclusive licence under the revised settlement agreement.

After receiving Apotex's letter, the FTC asked BMS to certify that it had not made "any representation, commitment, or promise to Apotex" that is not explicitly set out in the written revised settlement agreement – including regarding a promise not to launch an authorised generic. Mr Bodnar executed the certification and submitted it to the FTC.

The criminal investigation

Sometime after BMS had made its certification to the FTC (which was at odds with what was reported to the FTC by Apotex regarding BMS's commitment not to launch its authorised generic), the Department of Justice opened a criminal investigation into whether BMS, Mr Bodnar and others had made false statements to the FTC concerning the existence of an agreement not to launch an authorised generic. Under the direction of the Department, FBI agents raided BMS's offices, executing a search warrant that sought documents from the offices of Mr Bodnar, the then CEO Peter Dolan, the then general counsel Richard Willard, and others.

On 30 May 2007, the Department charged BMS with two counts of false statements for its submission of materials to the Federal Trade Commission. In the charging documents, the Department alleged that Mr Bodnar (referred to as "BMS Executive 1") had made oral representations to Apotex that caused Apotex to conclude that BMS would not launch an authorised generic in the event that the parties reached a final revised settlement agreement.

In June 2007, BMS entered into a plea agreement, in which it pled guilty to two false statements charges. The company admitted that it failed to disclose certain material information to the FTC in violation of 18 USC §1001. In April 2008, a grand jury charged Mr. Bodnar with making a false statement in violation of 18 USC §1001(a)(2) when he certified to the FTC that BMS had not made any representations to Apotex that BMS would not launch an authorised generic version of Plavix during Apotex's period of exclusivity.

Avoiding criminal exposure

The fundamental lesson of the *BMS/Bodnar* cases is a familiar one, but perhaps not familiar enough given the numerous high-profile prosecutions in recent years: do not lie to or mislead the government. In many law enforcement contexts, it is the lie or the deception, not the underlying conduct, that ultimately results in prosecution.

In the context of reporting patent settlement agreements to the FTC and the Department, the rules are the same – companies must be vigilant to report accurate information and not omit facts that are material to the reporting obligation. Counsel responsible for the filing should confirm from the client that there are no side agreements between the parties that are not part of the written agreement to be submitted to the agencies, or, if there are, then to disclose them. Such confirmation should include inquiry into whether the counterparty might misconstrue as a promise or commitment any statements made during the settlement negotiations that are not reduced to the written agreement. This type of analysis may be important because the counterparty has an independent obligation under the MMA to disclose all of the terms of the settlement agreement.

Ambiguities about facts or dueling interpretations of communications between parties (which may or may not have happened in the BMS/Apotex negotiations) understandably can lead to questions among FTC staff about an agreement's content or meaning. Companies would be well-advised to identify potential ambiguities in contract terms that might have competitive significance or in communications and try to resolve them with certainty. If possible, companies should resolve ambiguous language during the negotiation of the agreement and eliminate any ambiguities before signing. If that is not possible, then, in dealing with FTC staff, each party must be candid about how it interprets contract language, and why.

A broader lesson of these cases is that companies facing inquiries from antitrust authorities must take great care to ensure the accuracy of information being reported to those authorities during the course of any investigation. This is particularly true in the pharmaceutical industry, where the investigatory spotlight shines bright and is likely to continue to do so.

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