

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,)	Criminal No.:
)	
v.)	Filed:
)	
BRISTOL-MYERS SQUIBB COMPANY,)	Count 1: False Statement (18 U.S.C. § 1001)
)	Count 2: False Statement (18 U.S.C. § 1001)
Defendant.)	

INFORMATION

THE UNITED STATES OF AMERICA, ACTING THROUGH ITS ATTORNEYS,
CHARGES:

INTRODUCTION

Defendant and Relevant Parties

1. Bristol-Myers Squibb Company (“Defendant”) is an international pharmaceutical company which sells products throughout the world. Defendant is incorporated in the state of Delaware and maintains its corporate headquarters at 345 Park Avenue, New York, New York. Among many other brand name pharmaceuticals, Defendant participates in the sale and marketing of a brand name drug sold under the trade name Plavix®. Defendant participates in the sale and marketing of Plavix® through the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership. In 2006, the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership sold in excess of \$3.5 billion of Plavix® in the United States.

2. BMS Executive-1 is a former senior executive of Defendant who, in 2006, reported directly to Defendant’s then Chief Executive Officer and was a member of Defendant’s Executive Committee, which directly reported on matters to the Board of Directors.

3. In 2006, BMS Executive-1 had primary responsibility for negotiating a settlement

of patent litigation involving Plavix®. During that same time, he also represented Defendant on the Alliance Steering Committee of the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, which was a committee responsible for handling strategic issues relating to sales and marketing of Plavix® worldwide.

4. Apotex Inc. is a privately held Canadian pharmaceutical company with worldwide research, development, manufacturing and distribution facilities. The company is headquartered in Toronto, Canada. It sells and markets pharmaceuticals in the United States through Apotex Corporation. Apotex Inc. and Apotex Corporation are referred to herein collectively as “Apotex.”

5. Apotex Executive-1 is a senior executive of Apotex and is also an owner of the privately held company. Apotex Executive-1 was the person with primary responsibility for overseeing patent litigation involving Plavix® and the proposed settlement of that litigation.

6. Whenever in this Information reference is made to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or other representatives while they were actively engaged in the management, direction, control or transaction of its business or affairs.

Plavix®

7. Plavix®, a brand name pharmaceutical, was approved for sale in the United States by the U.S. Food and Drug Administration (“FDA”) in November 1997. Plavix® is prescribed for the reduction of thrombotic events, such as heart attacks and strokes, for patients who have recently suffered such events or who have arterial disease or acute coronary syndrome.

8. Sanofi-Synthelabo Inc., a subsidiary of Sanofi-Aventis (collectively “Sanofi”),

holds the approved New Drug Application (“NDA”) 20-839 for Plavix®, whose active ingredient is clopidogrel bisulfate. Sanofi obtained a patent claiming clopidogrel bisulfate on July 11, 1989. That patent, U.S. patent number 4,847,265 (“‘265 patent” or “Plavix® patent”), expires on November 17, 2011.

9. The ‘265 patent is exclusively licensed to the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, which, as the name indicates, is a partnership between Defendant and Sanofi. The Partnership is operated by consensus vote.

Sanofi-Synthelabo, et al. v. Apotex Inc., et al., 02 Civ. 255 (SHS)

10. In November 2001, Apotex filed an abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to manufacture and sell a generic form of the active ingredient in Plavix® (clopidogrel bisulfate) before the expiration of the ‘265 patent in November 2011. Apotex was the first to file an ANDA for clopidogrel bisulfate, thereby securing the right to 180 days of market exclusivity provided by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv), to the first ANDA filer to challenge a patent.

11. In response to Apotex’s ANDA filing, Defendant and Sanofi filed a lawsuit on March 21, 2002, challenging that Apotex’s filing of the ANDA infringed the ‘265 patent. Apotex filed a counterclaim in the suit alleging that the ‘265 patent was invalid. The lawsuit, captioned *Sanofi-Synthelabo, et al. v. Apotex Inc., et al.*, 02 Civ. 255 (SHS), is currently pending before the Honorable Sidney H. Stein in the U.S. District Court for the Southern District of New York.

Defendant’s Reporting Obligations

12. In April 2003, the Federal Trade Commission (“FTC”) and Defendant entered into

a consent order that, among other things, prohibited Defendant from settling any patent infringement litigation with any generic drug producer without first submitting the settlement agreement to the FTC for advisory approval that the settlement did not contain anticompetitive provisions (“FTC Consent Decree”).

The March Agreement

13. In or about January 2006, Defendant approached Apotex about the possibility of settling the Plavix® patent litigation, which was then scheduled for trial in April 2006.

14. The parties negotiated the terms of the first Plavix® patent settlement agreement (“March Agreement”) during the months of January to March 2006. In the negotiations, an important term that Apotex insisted on was Defendant’s commitment not to launch an authorized generic during the period of any license granted to Apotex.

15. On March 17, 2006, Defendant and Apotex executed the March Agreement. The March Agreement was subject to approval by the FTC under the terms of the FTC Consent Decree.

16. Under the March Agreement, Apotex was granted a license to manufacture and sell its generic version of Plavix® as of September 17, 2011 – two months before the Plavix® patent was due to expire on November 17, 2011. The March Agreement further provided that this license would be exclusive for a period of six months and specified that Defendant was precluded from launching an authorized generic version of Plavix® during that six-month period.

17. On April 4, 2006, the FTC met with outside counsel for Defendant about the March Agreement. At this meeting, the FTC objected to three provisions in the March Agreement. Specifically, the FTC objected to the provisions: (i) prohibiting Defendant from

launching an authorized generic version of Plavix® during the period of Apotex's exclusive license under the agreement; (ii) requiring that Defendant make a payment to Apotex of \$60 million if there was a "regulatory denial" (as that term was defined in the March Agreement) on or before June 30, 2006 ("break-up fee provision"); and (iii) requiring that Defendant compensate Apotex if annualized Plavix® sales did not reach specified minimum levels in the three months preceding Apotex's market entry in accordance with the March Agreement ("market guarantee provision").

18. On or around May 5, 2006, the FTC informed Defendant that it would reject the March Agreement because of the three objectionable provisions it had identified. Rather than reject the March Agreement, the FTC allowed Defendant to withdraw the March Agreement and try to renegotiate the terms with Apotex.

The Revised Agreement

19. The negotiations leading to the second iteration of the Plavix® patent settlement agreement (the "Revised Agreement") took place primarily during face-to-face meetings on May 12 and May 24, 2006, at Apotex's offices in Toronto, Canada. These meetings were attended on behalf of Defendant by BMS Executive-1 alone. Both the May 12 and May 24 meetings were attended on behalf of Apotex by Apotex Executive-1. Two other officers from Apotex participated in portions of the May 12 meeting.

20. During the meeting on May 12, 2006, the parties discussed that the FTC would not approve a revised settlement agreement that contained a written term committing Defendant not to launch an authorized generic. However, during that May 12 meeting, BMS Executive-1 made oral representations to Apotex for the purpose of causing Apotex to conclude that

Defendant would not launch an authorized generic in the event that the parties reached a final revised settlement agreement.

21. BMS Executive-1's oral representations to Apotex resulted in an understanding that Defendant would not launch an authorized generic version of Plavix® in the event that the parties reached a final settlement.

22. BMS Executive-1 met with Apotex again on May 24, 2006. At this meeting, the parties came to an agreement on the remaining terms of the Revised Agreement, subject to review of a final draft of the agreement.

23. The Revised Agreement was formally executed by Defendant on May 25, 2006. Apotex executed the Revised Agreement on May 26, 2006. Defendant submitted the Revised Agreement to the FTC for review and approval under the FTC Consent Decree on May 30, 2006.

24. The Revised Agreement did not include any mention of the three provisions from the March Agreement to which the FTC had objected: (i) the commitment not to launch an authorized generic version of Plavix® during Apotex's license period; (ii) the break-up fee; and (iii) the market guarantee.

25. Defendant's May 30, 2006, submission to the FTC did not disclose any oral representations or understandings regarding the launch of an authorized generic that occurred during the May 12, 2006 meeting.

26. On June 5, 2006, Apotex submitted the Revised Agreement to the FTC as required under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, Title XI, § 1112, 117 Stat. 2066 (Dec. 8, 2003), together with a letter disclosing certain oral agreements reached between Apotex and Defendant relating to the

Revised Agreement. In its letter, Apotex reported that it had reached an oral agreement with Defendant whereby Defendant agreed that it would not launch an authorized generic version of Plavix® during the license period granted to Apotex under the Revised Agreement.

FTC Certification

27. After receiving Apotex's disclosure, the FTC requested a written certification from Defendant confirming that Defendant "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 [DEFENDANT] would not launch an authorized generic version of Plavix[®] during Apotex's period of exclusivity."

28. The certification was executed and submitted to the FTC by Defendant on June 12, 2006. The certification was signed on behalf of Defendant by BMS Executive-1 and outside counsel and did not disclose any oral representations or understanding regarding the launch of an authorized generic that occurred during the May 12, 2006 meeting.

COUNT ONE
(False Statement)

THE UNITED STATES FURTHER CHARGES:

1. The United States realleges paragraphs 20-21 of this Information and incorporates by reference these paragraphs as if they were fully set forth herein.

2. Based on the foregoing, in a matter within the jurisdiction of the executive branch of the Government of the United States, Defendant knowingly and willfully falsified and concealed by trick, scheme and device a material fact and made a materially false, fictitious and fraudulent statement and representation, to wit, on May 30, 2006, in the District of Columbia, Defendant filed the Revised Agreement with the FTC, an agency within the executive branch of the United States, that failed to disclose certain information, including information set forth above in paragraphs 20 and 21, which was material to the FTC and, therefore, operated as an incomplete and false statement to the FTC.

3. The offense charged in this Count was carried out, in part, in the District of Columbia within the five years preceding the filing of this Information.

ALL IN VIOLATION OF TITLE 18, UNITED STATES CODE, SECTION 1001.

COUNT TWO
(False Statement)

THE UNITED STATES FURTHER CHARGES:

1. The United States realleges paragraphs 20-21, and 28 of this Information and incorporates by reference these paragraphs as if they were fully set forth herein.

2. Based on the foregoing, in a matter within the jurisdiction of the executive branch of the Government of the United States, Defendant knowingly and willfully made a materially false, fictitious and fraudulent statement and representation, to wit, on June 12, 2006, in the District of Columbia, the Defendant filed the certification referenced in paragraph 28 above with the FTC, an agency within the executive branch of the United States, that failed to disclose certain information, including information set forth above in paragraphs 20 and 21, which was material to the FTC and, therefore, operated as an incomplete and false statement to the FTC.

3. The offense charged in this Count was carried out, in part, in the District of Columbia within the five years preceding the filing of this Information.

ALL IN VIOLATION OF TITLE 18, UNITED STATES CODE, SECTION 1001.

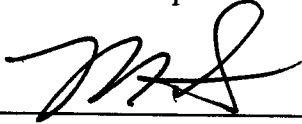
DATED: _____



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