

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,)	Criminal No: 08-CR-00115 RMU
)	
v.)	Filed: April 3, 2009
)	
ANDREW BODNAR,)	Count One: 18 U.S.C. § 1018
)	
Defendant.)	
)	

INFORMATION

COUNT ONE
(False Certificate)

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

1. At times material to this information:

Defendant and Bristol-Myers Squibb Company

a. Andrew BODNAR (“DEFENDANT”) held the position of Senior Vice President of Strategy and Medical and External Affairs at Bristol-Myers Squibb Company (“BMS”), an international pharmaceutical company which sells products throughout the world and maintains its corporate headquarters in New York, New York.

b. Among many other brand name pharmaceuticals, BMS participates in the sale and marketing of a brand name drug sold under the trade name Plavix.

c. In 2006, DEFENDANT had primary responsibility for negotiating a settlement of patent litigation involving Plavix.

Apotex

d. A privately-held Canadian pharmaceutical company, Apotex Corporation, headquartered in Toronto, Canada, has worldwide research, development, manufacturing and distribution facilities. Apotex Corporation sells and markets pharmaceuticals in the United States through its U.S. subsidiary, Apotex Incorporated. Apotex Corporation and Apotex Incorporated are referred to herein collectively as “Apotex.”

The Federal Trade Commission

e. The Federal Trade Commission (“FTC”) is an agency within the executive branch of the United States. The FTC is headed by five Commissioners, nominated by the President and confirmed by the Senate, each serving a seven-year term.

f. The FTC’s antitrust arm, the Bureau of Competition (“Bureau”), enforces federal antitrust laws, which prohibit anticompetitive mergers and other anticompetitive business practices in the marketplace.

Plavix

g. 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.

h. Sanofi-Synthelabo Inc., a subsidiary of Sanofi-Aventis (collectively “Sanofi”), holds a patent for the active ingredient in Plavix, clopidogrel bisulfate (the “’265 patent” or the “Plavix patent”). The ’265 patent is set to expire in or about November 2011.

i. The ’265 patent is exclusively licensed to a partnership between BMS and

Sanofi.

j. Whenever in this Information reference is made to any act, deed or transaction of any corporation or entity, the allegation means that the corporation or entity 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.

Patent Infringement Litigation

2. 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 or about November 2011.

3. Under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv), Apotex, as the first ANDA filer for clopidogrel bisulfate, was entitled to be the only generic company able to market its own generic version of Plavix for a period of 180 days (a period also sometimes referred to as 180 days of market exclusivity). Apotex would have no competition from a competing generic version of Plavix during the 180-day period, unless BMS and Sanofi decided to market what is called an “authorized generic” version of Plavix. The term “authorized generic” refers to a drug which is chemically identical to a brand-name drug and that the brand-name manufacturer authorizes to be marketed as a generic.

4. In response to Apotex’s ANDA filing, BMS and Sanofi filed a lawsuit on or about March 21, 2002, alleging 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.

BMS’s Reporting Obligations

5. In or about April 2003, the FTC and BMS entered into a consent order that, among other things, prohibited BMS 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”). BMS also was required by law to submit any settlement agreement with a generic drug producer to the FTC 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) (“MMA”).

The March Agreement

6. In early 2006, BMS approached Apotex about the possibility of settling the Plavix patent litigation.

7. On or about March 17, 2006, BMS, Sanofi and Apotex executed the first Plavix patent settlement agreement (“March Agreement”). The March Agreement was subject to approval by the FTC under the terms of the FTC Consent Decree.

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

9. On or about April 4, 2006, the FTC met with outside counsel for BMS about the March Agreement. At this meeting, the FTC objected to the contractual provision in the March Agreement prohibiting BMS from launching an authorized generic version of Plavix during the period of Apotex’s exclusive license under the agreement.

10. In early May 2006, BMS withdrew the March Agreement from consideration by the FTC in light of the FTC's objections.

The Revised Plavix Agreement

11. The negotiations leading to the second version of the Plavix patent settlement agreement ("Revised Plavix Agreement") took place primarily during face-to-face meetings on or about May 12 and May 24, 2006, at Apotex's offices in Toronto, Canada ("May Meetings"). DEFENDANT went alone to the May Meetings to negotiate the Revised Plavix Agreement with Apotex.

12. During the May Meetings, the parties discussed that the FTC would not approve a Revised Plavix Agreement that contained a written term committing BMS not to launch an authorized generic. However, during the meeting on May 12, DEFENDANT made representations to Apotex to reassure it that BMS would not launch an authorized generic version of Plavix during Apotex's period of exclusivity in the event that the parties reached a Revised Plavix Agreement.

13. The Revised Plavix Agreement was formally executed by BMS on or about May 25, 2006. DEFENDANT executed the Revised Plavix Agreement on behalf of BMS. Apotex executed the Revised Plavix Agreement on or about May 26, 2006. BMS submitted the Revised Plavix Agreement to the FTC under the MMA and for review and approval under the FTC Consent Decree on or about May 30, 2006.

14. BMS's MMA and FTC Consent Decree submissions on or about May 30, 2006, to the FTC did not disclose any of the representations made by DEFENDANT regarding the launch of an authorized generic that occurred during the meeting on May 12.

15. On or about June 5, 2006, Apotex submitted the Revised Plavix Agreement to the

FTC as required under the MMA, together with a letter disclosing certain alleged oral agreements reached between Apotex and BMS relating to the Revised Plavix Agreement. In its letter, Apotex alleged that it had reached an oral agreement with BMS whereby BMS agreed that it would not launch an authorized generic version of Plavix during the license period granted to Apotex under the Revised Plavix Agreement.

FTC Certification

16. After receiving Apotex's MMA disclosure, the FTC, as authorized by the MMA and the FTC Consent Decree, requested a written certification from BMS, confirming that BMS "has not made any representation, commitment, or promise to Apotex, whether oral or written, that is not explicitly set forth in the Revised Plavix Agreement, including the representation that [BMS] would not launch an authorized generic version of Plavix during Apotex's period of exclusivity."

17. The FTC authorized DEFENDANT, as "the BMS representative involved in, and responsible for, the negotiations with Apotex concerning the [Revised Plavix Agreement]," to execute the certification on behalf of BMS.

18. The certification was executed by DEFENDANT and submitted to the FTC's offices in the District of Columbia on or about June 12, 2006.

Description of the Offense

19. On or about June 12, 2006, DEFENDANT, Andrew BODNAR, an officer of BMS and a person authorized by the FTC under the FTC Consent Decree and MMA to certify the terms of the Revised Plavix Agreement, knowingly made and delivered as true a writing to the FTC in the District of Columbia containing a statement which he knows is false. Specifically, the DEFENDANT knowingly signed a written certification dated June 12, 2006, in his capacity as

Senior Vice President of BMS that stated that no representations had been made to Apotex that BMS would not launch an authorized generic version of Plavix during Apotex's period of exclusivity, when representations were made by the DEFENDANT to Apotex to reassure it that BMS would not launch an authorized generic version of Plavix during Apotex's period of exclusivity in the event that the parties reached a Revised Plavix Agreement. The DEFENDANT caused this certification to be delivered to the FTC in the District of Columbia.

ALL IN VIOLATION OF TITLE 18, UNITED STATES CODE, SECTION 1018.

DATED: April 3, 2009

/s/
SCOTT D. HAMMOND
Acting Assistant Attorney General
Antitrust Division
United States Department of Justice

/s/
MARC SIEGEL
Director of Criminal Enforcement
Antitrust Division
United States Department of Justice

/s/
LISA M. PHELAN
Chief, National Criminal Enforcement Section
Antitrust Division
United States Department of Justice

/s/
JOHN F. TERZAKEN III
BRENT SNYDER
PORTIA BROWN
SHANE CRALLE
Trial Attorneys
Antitrust Division
United States Department of Justice