

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

Holding a Criminal Term

Grand Jury Sworn in on November 3, 2006

UNITED STATES OF AMERICA,	:	CRIMINAL NO.
	:	
v.	:	GRAND JURY 06-3
	:	
ANDREW BODNAR,	:	VIOLATION: 18 U.S.C. § 1001(a)(2)
	:	
Defendant.	:	
	:	

**INDICTMENT**

**COUNT ONE**  
**(False Statement)**

THE GRAND JURY CHARGES:

1. At times material to this indictment:

**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 Indictment 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").

### **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 Agreement**

11. The negotiations leading to the second version of the Plavix patent settlement agreement (“Revised 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 Agreement with Apotex.

12. During the May Meetings, the parties discussed that the FTC would not approve a Revised Agreement that contained a written term committing BMS not to launch an authorized generic. However, during the May Meetings, 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 Agreement.

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

14. BMS’s submission 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 May Meetings.

15. On or about 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) (“MMA”), together with a letter disclosing certain oral agreements reached between Apotex and BMS relating to the

Revised Agreement. In its letter, Apotex reported 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 Agreement.

#### **FTC Certification**

16. After receiving Apotex's MMA disclosure, the FTC requested a written certification from "Sanofi," a term defined in the opening line of the certification to include BMS, confirming that "Sanofi 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 Sanofi would not launch an authorized generic version of Plavix during Apotex's period of exclusivity."

17. The certification was executed for "Sanofi" by DEFENDANT and submitted to the FTC on or about June 12, 2006.

#### **Description of the Offense**

18. The existence of representations made by 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 Agreement, was a material fact in connection with the certification requested by the FTC as part of its consideration of the Revised Agreement under the FTC Consent Decree.

19. On or about June 12, 2006, in the District of Columbia and elsewhere, the DEFENDANT, Andrew BODNAR, did knowingly and willfully make a materially false, fictitious, and fraudulent statement and representation in a matter within the jurisdiction of the FTC, an agency within the executive branch of the United States, in that DEFENDANT certified

to the FTC that “Sanofi,” a term defined in the opening line of the certification to include 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 Sanofi would not launch an authorized generic version of Plavix during Apotex’s period of exclusivity.”

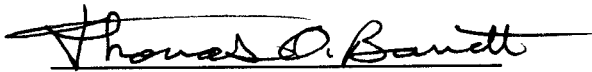
20. As DEFENDANT well knew when it was made, this statement was false in that during the May Meetings, DEFENDANT made representations to Apotex to reassure it that BMS would not launch an authorized generic version of Plavix during Apotex’s period of exclusivity in the event that the parties reached a Revised Agreement.

ALL IN VIOLATION OF TITLE 18, UNITED STATES CODE, SECTION 1001(a)(2).


A TRUE BILL:


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FOREPERSON

DATED: \_\_\_\_\_

  
THOMAS O. BARNETT  
Assistant Attorney General  
Antitrust Division  
United States Department of Justice

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JOHN F. TERZAKEN III  
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LISA M. PHELAN  
Chief, National Criminal Enforcement Section  
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