UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

APOTEX PHARMACEUTICAL HOLDINGS, INC., a Canadian corporation and APOTEX CORP., a Delaware corporation,

Plaintiffs,

vs.

SANOFI-AVENTIS, a corporation of France, SANOFI-SYNTHELABO, INC., a Delaware corporation, BRISTOL-MYERS SQUIBB COMPANY, a Delaware corporation and BRISTOL-MYERS SQUIBB SANOFI-PHARMACEUTICALS HOLDING PARTNERSHIP, a Delaware corporation,

Defendants.
_____/

CASE NO.: _____
09-CV-61575-Cohn-Seltzer

FILED by VT D.C.
ELECTRONIC
Oct. 2, 2009
STEVEN M. LARIMORE
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT, UNENFORCEABILITY AND FOR BREACH OF CONTRACT

For their Complaint, Plaintiffs Apotex Pharmaceutical Holdings, Inc. and Apotex Corp. (collectively, "Apotex"), allege as follows.

NATURE OF THE ACTION

1. This is an action for a declaratory judgment of post-grant unenforceability due to patent misuse of/criminal acts regarding United States Patent No. 4,847,265 ("the '265 patent"), and for breach of contract.

PARTIES

2. Plaintiff Apotex Pharmaceutical Holdings, Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada. Apotex

Pharmaceutical Holdings, Inc. is a pharmaceutical company that specializes in offering life-saving, generic medications to consumers at a lower cost than branded medications.

3. Plaintiff Apotex Corp. is a Delaware corporation registered to do business in Florida, having a place of business within this district at 2400 North Commerce Parkway, Weston, Florida 33326. Apotex Corp. is the U.S. company that imported, marketed and sold a generic clopidogrel bisulfate medication in the U.S. as an alternative to Plavix®.

4. Defendant Sanofi-Aventis is a corporation organized and existing under the laws of France, having a place of business at 174 avenue de France, 75635-Paris cedex 13, France. Sanofi-Aventis is a pharmaceutical company which specializes in the sale and manufacture of branded medications like Plavix®.

5. Defendant Sanofi-Synthelabo, Inc. ("Synthelabo") is a Delaware corporation having a place of business at 90 Park Avenue, New York, New York 10016. Synthelabo is a pharmaceutical company which specializes in the sale and manufacture of branded medications like Plavix®.

6. Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation having a place of business at 345 Park Avenue, New York, New York 10154. BMS is a pharmaceutical company which specializes in the sale and manufacture of branded medications like Plavix®.

7. Defendant Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (the "Partnership") is a Delaware partnership controlled by BMS and Sanofi having a mailing address at P.O. Box 4000, Route 206 and Province Line Road, Princeton, New Jersey 08543. The Partnership was formed by BMS and Sanofi for the purpose of marketing and selling Plavix®.

8. Defendants Sanofi-Aventis, Synthelabo, BMS and the Partnership are referred to herein collectively as "Defendants."

JURISDICTION AND VENUE

9. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* and under the patent laws of the United States, Title 35 of the United States Code. The Court has jurisdiction over this action pursuant to 35 U.S.C. §§ 271, *et seq.*, and 28 U.S.C. §§ 1331, 1338, and 2201-2202.

10. This Court has personal jurisdiction over each of the Defendants by virtue of the business activities it conducts within the State of Florida and within this District, including the marketing and sale of Plavix®, resulting in sufficient minimum contacts with this forum.

11. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) because each of the Defendants is a corporation and because this Court has personal jurisdiction over each of the Defendants.

COUNT I

DECLARATORY JUDGMENT OF PATENT UNENFORCEABILITY

(Post-Grant Unenforceability Due To Patent Misuse/ Criminal Acts)

12. Apotex incorporates paragraphs 1-11 by reference as if fully set forth herein.

13. The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 ("FDCA"), provides that a company wishing to market a new brand-name drug must submit a New Drug Application, known as an NDA, to the Food and Drug Administration. See *Id.*§ 355(b)(1).

14. In 1984, Congress passed the "Hatch-Waxman" amendments to the FDCA. *See* The Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35, and 42 U.S.C.). Enacted to expedite the process by which companies gain approval to sell generic versions of already-

approved brand-name drugs, the amendments allow companies seeking such approval to submit Abbreviated New Drug Applications, known as ANDAs, that "piggyback" on the safety-and-effectiveness information that the brand-name manufacturers submitted in their New Drug Applications ("NDA"). *See* 21 U.S.C. § 355(j)(2)(A).

15. Owners of NDAs must list patents that allegedly cover the brand-name drug in the FDA's so-called "Orange Book." An ANDA filer must make one of four certifications to the FDA regarding patents: "(I) that no patent has been filed with the FDA; (II) that the patent has expired; (III) that the patent will expire on a date certain; (IV) that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12)(i).

16. Synthelabo holds approved NDA 20-839 for Plavix®, a brand name for clopidogrel bisulfate. Synthelabo listed the '265 patent, and other patents not important for purposes of this Count, in the FDA's "Orange Book".

17. Apotex submitted an ANDA to market a generic version of Plavix®. At the time the ANDA was filed, the FDCA provided that that the first company to seek FDA approval of an ANDA containing a paragraph IV certification has the right to sell its drug without competition for 180 days. *Id.* § 355(j)(5)(B)(iv). This 180 day exclusivity was intended as an incentive to generic drug applicants to risk litigation in order to encourage Paragraph IV challenges, thereby increasing the availability of low-cost generic drugs. During this 180 day window, the FDA could not make effective the approval of any other ANDA for the drug in question that contains a paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

18. Apotex was the first to file a complete ANDA with a Paragraph IV certification challenging the validity of the '265 patent. Thus, Apotex was entitled to the 180 day exclusivity under § 355(j)(5)(B)(iv).

19. Apotex's right to the 180 day exclusivity had substantial value at all times material to this Count.

20. As set forth herein, Defendants and others conspired to unlawfully deprive Apotex of its 180 day exclusivity to market a generic version of Plavix® during the relevant time frame.

21. In 2002, Defendants sued Apotex for patent infringement in the Southern District of New York. *Sanofi-Synthelabo v. Apotex, Inc.*, No. 02-cv-2255 (SHS) (S.D.N.Y.) ("the patent infringement lawsuit.")

22. By January 2006, Defendants realized that the defenses Apotex had asserted in the patent infringement lawsuit had placed the validity of their '265 patent at risk. Defendants realized that a holding that the '265 patent was invalid would have caused them a loss of billions of dollars of revenue.

23. By January 2006, Defendants had also learned that Apotex had been approved by the FDA to market its generic product.

24. Thus, in January 2006, Defendants sought to entice Apotex to settle the patent infringement lawsuit by offering an agreement that would have preserved Apotex's 180 day exclusivity and which would have resulted in Apotex being able to market its generic version of Plavix® before the expiration of the '265 patent.

25. After further investigation and discovery, there is likely to be evidence that, in furtherance of said conspiracy, Defendants entered into an agreement with at least one third party

in which a license under the '265 patent to such third party to market an "authorized" generic version of Plavix® was tied to and conditioned on the FDA's authorization to Apotex to sell Apotex's ANDA product, and the actual sales by Apotex of such product, the timing of which would have resulted in depriving Apotex of its exclusive right under the Hatch Waxman Act to market a generic version of Plavix® for 180 days.

26. Apotex was led to believe by statements made by agents of Defendants that Defendants intended to launch an authorized generic if Apotex sold its generic version of Plavix® before the expiration of the '265 patent, and thus deprive Apotex of a substantial part of the economic value of the 180 day exclusivity period.

27. On March 17, 2006, Apotex entered into an agreement ("the March 2006 Agreement") with Defendants (referred to collectively in the March 2006 Agreement as "Sanofi") concerning a license agreement for the '265 patent.

28. The March 2006 Agreement also included Defendants' promise not to market an authorized generic and a break-up fee provision of $60 million if the agreement was not approved on or before June 30, 2006.

29. The March 2006 agreement, however, was not approved by the FTC and other governmental entities.

30. On May 26, 2006, Apotex entered into another agreement ("the May 2006 Agreement") with Defendants (referred to collectively in the May 2006 Agreement as "Sanofi") concerning a license agreement for the '265 patent, but the May 2006 Agreement did not include a written promise by Defendants not to market an authorized generic. However, Defendants provided Apotex with an oral commitment that it would not market an authorized generic during

the period of Apotex's exclusivity. A copy of the May 2006 Agreement is attached hereto as Exhibit A.

31. Under a decision and order dated April 14, 2003, *In the matter of Bristol-Myers Squibb Company*, FTC Docket No. C-4076, 135 F.T.C. 444, 486 (2003) ("the FTC Order"), and the Consent Order and Stipulated Injunction dated April 14, 2003, in *State of Ohio et al v. Bristol-Myers Squibb Company*, 1:02-CV-01080 (D.D.C.), BMS was required to report any agreement settling litigation over any patent covering a drug to the FTC and state attorneys general. Paragraph XII of the FTC Order provides, in part, that BMS is prohibited from entering into final settlements of patent litigation in which (1) it provides "something of value" to a potential generic entrant, and (2) the generic agrees not to sell its product for some period of time.

32. A proviso to Paragraph XII provides an exception, under which BMS can resolve or settle such litigation after the Commission, in response to a request by BMS for an advisory opinion pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. §1.2, determines that the settlement agreement would not raise issues under Section 5 of the FTC Act, 15 U.S.C. §45.

33. Under Title XI, Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law. 108-173, 117 Stat. 2461 (Dec. 8, 2003) ("MMA"), Sections 1112(c), in 2006, each party to a settlement of patent litigation must disclose the complete terms of settlements of the patent litigation to the FTC and the Department of Justice.

34. Section 1112 (c)(3) of the MMA requires that each of the parties involved in the settlement of a patent infringement case "shall file written descriptions of such agreement that

are sufficient to disclose all of the terms and conditions of the agreement" including those terms that are not reduced to writing.

35. Section 1115 of the MMA provides that a brand name drug company or generic drug applicant which fails to comply with any provision of the MMA "shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of the subtitle."

36. On June 5, 2006, Apotex notified the FTC of the terms of the May 26, 2006 agreement, both written and oral.

37. On May 30, 2007, a criminal Information was filed against BMS, namely *U.S. v. Bristol-Myers Squibb Company*, No. 1:07-cr-00140 (D.D.C., May 30, 2007). A copy of the Information is attached hereto as Exhibit B.

38. In the Information, the government made the following allegations:

> **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.

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 [A]greement, 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.

39. BMS pleaded guilty to the Information and was adjudged guilty on June 14, 2007. A copy of the Judgment In A Criminal Case is attached hereto as Exhibit C.

40. By pleading guilty, BMS admitted that it made false statements to the FTC for the purpose of concealing anticompetitive provisions of a license agreement for the '265 patent, which BMS knew would be considered by the FTC to be anticompetitive, and thus be considered by the FTC to violate 15 U.S.C. § 45(a) and prior consent decrees.

41. On March 26, 2009, the Federal Trade Commission brought a civil action against BMS under 15 U.S.C. § 45 for civil penalties for violations of a final order to cease and desist

and under the MMA. *FTC v. Bristol-Myers Squibb Company*, No. 1:09-cv-00576 (D.D.C.). A copy of the Complaint For Civil Penalties Pursuant To Section 5(l) Of The Federal Trade Commission Act is attached hereto as Exhibit D.

42. Citing the facts pleaded in the Information and admitted by BMS, the FTC also pleaded in paragraph 48 of its Complaint that "BMS was in continuous violation of the second proviso to Paragraph XII of the [FTC Order] from May 30, 2006, the date it submitted the revised settlement agreement with its request for an advisory opinion, until at least August 31, 2006, the date it obtained a preliminary injunction against Apotex." *See* Exhibit D.

43. Also, citing the facts pleaded in the Information and admitted by BMS, the FTC further pleaded in paragraph 53 of its Complaint that "BMS was in continuous violation of Section 1112(c) (3) of the MMA from May 30, 2006, the date it submitted the revised settlement agreement required by Section 1112(a) of the MMA until at least August 31, 2006, the date it obtained a preliminary injunction against Apotex." *See* Exhibit D.

44. On March 26, 2009, the same day the FTC's Complaint was filed, BMS stipulated that the Court may file and enter a final judgment, in which BMS agreed to pay a civil penalty of $2,100,000. *See* Exhibit D.

45. On March 30, 2009, the Court entered the final judgment which included the requirement that BMS pay a civil penalty of $2,100,000. A copy of the Final Judgment is attached hereto as Exhibit E.

46. The May 2006 Agreement entered into by the Defendants and Apotex included written provisions granting Apotex a license under the '265 patent, requiring the parties to "use reasonable efforts to continue the Regulatory Review to address such objection and to obtain

Regulatory Clearance" of the agreement by the FTC and other government entities, and setting a limit on damages for patent infringement.

47. In addition, as is reflected in a June 5, 2006 letter sent on behalf of Apotex to the FTC, Defendants made oral commitments that no authorized generic would be launched during Apotex's period of exclusivity, if the agreement is approved by the FTC, and that Apotex's signing of the new agreement is not to be taken as a waiver by Apotex of its now-vested right to the $60 million Apotex was owed under the previous agreement.

48. BMS was obligated under the terms of both the FTC Order and the MMA to accurately and fully report each and every term and condition, written and oral, of any agreement settling its claim that the '265 patent would be infringed by Apotex's ANDA formulation. BMS was thus obligated to disclose the May 2006 Agreement and license of the '265 patent and any oral agreements relating thereto, so that the FTC and other government agencies would have the opportunity to consider whether the entire agreement, written and oral, included provisions that it might consider anticompetitive and in violation of 15 U.S.C. § 45(a), which prohibits, *inter alia*, "unfair methods of competition," and which includes any conduct that would violate the Sherman Antitrust Act.

49. Defendants Sanofi-Aventis and the Partnership are parties to the May 2006 Settlement Agreement.

50. After a reasonable opportunity for further discovery, there is likely to be evidence that all Defendants were aware of and participated in the drafting of the May 2006 Settlement Agreement and in BMS' decision to orally agree not to market an authorized generic equivalent to Plavix®.

51. The foregoing conduct constituted silence in the face of a duty to disclose and patent misuse from at least May 30, 2006, *i.e.*, the date BMS submitted the revised settlement agreement required by Section 1112(a) of the MMA, until at least August 31, 2006, *i.e.*, the date on which Defendants obtained a preliminary injunction against Apotex, rendering the '265 patent unenforceable until such misuse was cured.

52. Any sales by Apotex of its generic version of Plavix® occurred during the period when the '265 patent was unenforceable, and Defendants cannot collect damages for sales of generic equivalents of Plavix® during the period that the patent was unenforceable due to patent misuse.

53. In view of the foregoing, an actual and justiciable controversy exists between Apotex on the one hand, and Defendants on the other, as to whether the '265 patent was unenforceable due to patent misuse. A judicial declaration is necessary and appropriate so that Apotex may ascertain its rights regarding the '265 patent.

COUNT II

BREACH OF CONTRACT

54. Plaintiffs incorporate by reference the allegations paragraphs 1-53 as if fully set forth herein.

55. Apotex entered into a valid and enforceable contract with Defendants when it executed the May 2006 Settlement Agreement on or around May 26, 2006.

56. Paragraph 13 of the May 2006 Settlement Agreement requires that "[t]he parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner."

57. Paragraph 13 of the May 2006 Settlement Agreement further instructs that "[i]f the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain Regulatory Clearance...".

58. Apotex performed its obligations under the May 2006 Settlement Agreement.

59. Defendants breached the May 2006 Settlement Agreement by failing to cooperate with the Government, by failing to use reasonable efforts to facilitate the review in the face of the Government's request for additional information via certification, and by giving false material information to the Government.

60. Instead of truthfully negotiating with the Government, Defendants submitted a false written certification to the Government that destroyed any chance of obtaining Regulatory Clearance and deprived Apotex of the tangible benefits of the May 2006 Settlement Agreement.

61. As a result of Defendants' breach of the May 2006 Settlement Agreement, Apotex was damaged.

62. BMS's breach of the May 2006 Settlement Agreement evidenced a high degree of moral turpitude and demonstrates such wanton dishonesty as to imply a criminal indifference to civil obligations.

63. The false statements BMS made to the FTC on behalf of Defendants in breach of the May 2006 Settlement Agreement were aimed at the public generally because they concealed oral terms of the May 2006 Settlement Agreement that BMS knew were considered by the FDA to be anticompetitive.

WHEREFORE, Apotex prays that this Court enter judgment in its favor and against Defendants as follows:

A. That Defendants be temporarily restrained and preliminarily enjoined from further prosecution of any claim for damages related to alleged infringement of the '265 patent until after the trial in this case;

B. That this Court combine the trial in this case with the preliminary injunction hearing;

C. For damages in an amount to be proved at trial, plus pre- and post-judgment interest, reasonable costs, expenses, and attorneys' fees;

D. That the '265 patent was unenforceable for patent misuse during the period of time that Apotex sold the accused product;

E. That this Court order that entry of any judgment in favor of the Defendants in any matter against Apotex for infringement of the patent that was subject of the May 2006 agreement be stayed pending resolution of this matter.

F. And for such other relief that the Court deems just and proper.

TRIAL BY JURY DEMAND

Pursuant to Rule 38, Fed. R. Civ. P., Apotex demands a trial by jury.

Dated: October 2, 2009

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By: _____

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Attorneys for Plaintiffs Apotex Inc. and Apotex Corp.

EXHIBIT A

Settlement Agreement

Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms:

1. As used herein, the term "Sanofi" refers to Sanofi-Aventis, Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company, and the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, collectively and individually, and the term "Apotex" refers to Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.

2. Prior to completion of the Regulatory Review referred to in paragraph 13, the terms of this agreement are and remain confidential and will not be disclosed or used except as required by law or to effectuate the agreement, provided, however, that prior to the end of that review period, Sanofi may disclose the material terms of the agreement in anticipation of, and prior to, an official government request. If Sanofi discloses any of the terms in a manner to make them publicly available, the requirement of confidentiality as to those terms shall expire. If any party wishes to issue a press release, it will first make the text available to all other parties.

3. The pending litigations between Apotex and Sanofi will be terminated by dismissal, without prejudice, of the complaints and all counterclaims, and Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations.

4. Apotex is granted a license, under the '265 patent, effective on June 1, 2011 to make, use, import, sell and offer for sale its clopidogrel bisulfate ANDA product in the United States but without the right to grant sub-licenses and Sanofi will not waive its pediatric exclusivity with respect to any other ANDA filer prior to January 31, 2012. However, if Sanofi does not obtain pediatric exclusivity for its clopidogrel bisulfate product by March 15, 2011, then Apotex's license shall become effective on April 1, 2011.

5. In the event that Sanofi launches a drug product (other than Plavix), an active ingredient of which is an anti-platelet aggregation agent, in the United States, prior to the effective date of Apotex's license under the '265 Patent, then Apotex shall be granted a license to make, use, offer for sale, sell, and import such drug product in the United States, under all patents applicable to that drug product owned by or licensed to Sanofi, effective on the date which is the effective date of Apotex's license under the '265 Patent pursuant to this agreement.

6. If, through the action of another entity, every basis for Apotex's sole market exclusivity for clopidogrel bisulfate under 21 U.S.C. § 355(j)(5) is triggered before the date specified in paragraph 4, then the license granted to Apotex in paragraph 4 shall commence on that earlier date.

7. Apotex agrees that neither it, nor any lawyers, officers, employees, or fact or expert witnesses who are under Apotex's control will assist, encourage or provide

any information to any party in attacking the '265 patent except as compelled by law.

8. If an event has occurred that Apotex, in good faith, believes poses a credible threat to constitute a trigger of every basis on which Apotex would have sole exclusivity for clopidogrel bisulfate under the Hatch-Waxman Act, Apotex shall inform Sanofi, giving Sanofi full details thereof. Sanofi shall have 30 days within which to decide whether to accelerate the effective date of Apotex's license. For purposes of this paragraph, "trigger" shall mean forfeiture, cancellation, or loss for any reason. If Sanofi elects not to accelerate the effective date of Apotex's license, and Apotex takes all reasonable steps, as Sanofi directs and at Sanofi's expense, to contest the loss of that exclusivity, and there is a final determination that the event did cause Apotex to lose all or any portion of that exclusivity, Sanofi will compensate Apotex for the economic loss Apotex suffered as a result of the failure to accelerate Apotex's license, the amount of such loss to be determined by arbitration in New York City under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by the American Arbitration Association who shall have at least 10 years experience, with the arbitrator's fee to be shared equally by Apotex and Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment.

9. Apotex agrees that it will not sell any clopidogrel product in the United States prior to the date its license under the '265 patent becomes effective. Apotex further agrees that any breach by it of this provision will cause irreparable harm to Sanofi. Apotex hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Apotex irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.

10. As compensation to Apotex for Apotex's investment in inventory, Sanofi will reimburse Apotex for Apotex's stock of clopidogrel bisulfate bulk and finished goods that are in Apotex's actual possession as of March 31, 2006, for a price not to exceed $40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance (as defined in paragraph 13) with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly. Upon execution of this agreement, Apotex will cease writing purchase orders to Signa and will advise Signa not to ship any additional bulk clopidogrel bisulfate until further notice. Apotex will, at Sanofi's election and expense, either deliver to Sanofi, or destroy, all or any portion of that inventory, up to the value of $40 million.

11. To relieve Apotex from the risk of liability under its agreement with Signa to purchase bulk clopidogrel bisulfate, Sanofi agrees to negotiate in good faith with Signa to obtain a release, for fair value, of any claims that Signa has against Apotex under the Apotex/Signa contract dated June 30, 2000. It is understood, however, that Sanofi is not required by this provision to assume Apotex's obligations or otherwise step into Apotex's shoes under the contract. If a release has not been agreed within 90 days after Regulatory Clearance is obtained, then either Signa or Sanofi may submit the matter to binding arbitration to determine that fair value under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by AAA, who shall have at least 10 years experience, with the arbitrator's fee to be paid by Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment. If Signa refuses to accept the provisions of this paragraph, then Sanofi agrees to defend Apotex against a suit by Signa with counsel chosen by Sanofi, and (provided Sanofi controls the defense of such suit) to indemnify Apotex against any award or settlement resulting from that suit. Signa will have the right to enforce the provisions of this paragraph. Apotex will not participate in or advise Signa in connection with the negotiations. However, Apotex may provide any information that is requested by either Sanofi or Signa, provided Apotex provides that information equally and simultaneously to both Sanofi and Signa. Apotex warrants that neither it nor anyone affiliated with or employed by Apotex will receive directly or indirectly, any financial benefit from any settlement or agreement between Sanofi and Signa. Apotex warrants that the June 30, 2000 contract is the only agreement that Apotex has with Signa or any other supplier that relates to clopidogrel bisulfate except for an agreement dated October 15, 2000 between Brantford Chemicals Inc. and Signa, but Apotex warrants that Apotex will not receive any benefit under that agreement as the result of any negotiation or agreement between Sanofi and Signa pursuant to this paragraph.

12. It is expressly understood that, except as provided in paragraph 5 above, no license is granted under any other patent owned or controlled by Sanofi.

13. This agreement is subject to regulatory review by the FTC and state attorneys general ("Regulatory Review"). The parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner. The provisions of paragraphs 3-12 of this agreement shall not be or become effective unless and until: (a) the FTC issues an advisory opinion determining that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act, and (b) the state attorneys general provide written notice that they do not object to the agreement, (a) and (b) together constituting "Regulatory Clearance". If the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain Regulatory Clearance, provided that there shall be no material change to the rights and obligations of the parties under this agreement except as they may mutually agree. "Regulatory Denial", as used herein, shall mean a denial of approval by

either of the FTC or a state attorney general as to which neither party seeks further review. If Regulatory Review has not been completed by July 31, 2006, either party has the right to declare that there has been Regulatory Denial.

14. In the event of Regulatory Denial, the litigations will be resumed as further described in paragraph 15 hereof, and:

(i) Sanofi will compensate Apotex by reimbursing Apotex for its fully loaded cost for any clopidogrel bisulfate inventory in Apotex's possession that has less than one year of remaining shelf life as of the end of each of those months, provided, however, that Apotex shall relabel its inventory to the extent possible to extend its expiration date, and Sanofi shall pay Apotex an amount not to exceed $500,000 to effectuate that relabelling, .

(ii) If the litigation results in a judgment that the '265 patent is not invalid or unenforceable, Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 50% of Apotex's net sales of clopidogrel products if Sanofi has not launched an authorized generic and 40% of Apotex's net sales if Sanofi has launched an authorized generic. Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.

15. Sanofi and Apotex will jointly request that the court maintain the litigation between them on the court's suspense docket to permit the Regulatory Review of this agreement. If the Regulatory Review results in Regulatory Denial, Sanofi and Apotex will jointly request that the court reset the trial date to a date that is not earlier than 2 ½ months from the date on which the request is made. Apotex agrees that it will not launch a generic clopidogrel product during the time of the Regulatory Review and Sanofi agrees it will not launch an authorized generic clopidogrel product during the time of the Regulatory Review. The parties agree that they shall jointly seek issuance of a court order embodying the provisions of this paragraph. Further, it is agreed that if the Regulatory Review results in Regulatory Denial then,

(i) Until 5 business days after the date on which Regulatory Denial is effective (not counting the day on which it becomes effective), Apotex will not launch a generic clopidogrel product and Sanofi will not launch an authorized generic product, and Sanofi will not seek a temporary restraining order or a preliminary injunction.

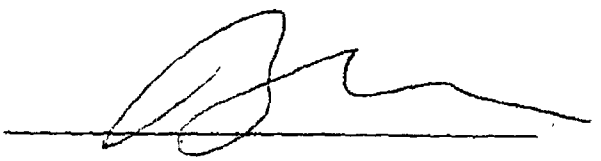
(ii) After the expiration of the period defined in sub-paragraph (i), Sanofi agrees that it will not launch an authorized generic clopidogrel product before a launch by Apotex of a

generic clopidogrel product, and Sanofi will not, at any time, file for a temporary restraining order, and will not file for a preliminary injunction until Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product.

16. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful

17. This agreement may be executed in counterparts by each of the parties hereto.

Signed and agreed on May 26, 2006

For Apotex Inc and Apotex Corp. 

For Sanofi-Aventis _____

For Bristol-Myers Squibb Company _____

For Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership _____

_____

_____

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generic clopidogrel product, and Sanofi will not, at any time, file for a temporary restraining order, and will not file for a preliminary injunction until Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product.

16. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful.

17. This agreement may be executed in counterparts by each of the parties hereto.

Signed and agreed on May 25 2006

For Apotex Inc and Apotex Corp.

For Sanofi-Aventis

For Bristol-Myers Squibb Company

For Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership

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generic clopidogrel product, and Sanofi will not, at any time, file for a temporary restraining order, and will not file for a preliminary injunction until Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product.

16. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful

17. This agreement may be executed in counterparts by each of the parties hereto.

Signed and agreed on May 25 2006

For Apotex Inc and Apotex Corp. _____

For Sanofi-Aventis _____

For Bristol-Myers Squibb Company _____

For Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership _____

_____

_____

NY_Main 558460_v2

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	Criminal No.: 07-140
	)	
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:

LAMBERTH, J. RCL

RECEIVED
MAY 30 2007
NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

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: May 30, 2007

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

JOHN F. TERZAKEN III
BRENT C. SNYDER
PORTIA BROWN
Trial Attorneys
Antitrust Division
United States Department of Justice

SCOTT D. HAMMOND
Deputy Assistant Attorney General
Antitrust Division
United States Department of Justice

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

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

EXHIBIT C

AO 245E (Rev. 12/03) Judgment in a Criminal Case for Organizational Defendants
Sheet 1

UNITED STATES DISTRICT COURT

District of

UNITED STATES OF AMERICA
V.

BRYSTOL-MYERS SQUIBB COMPANY

JUDGMENT IN A CRIMINAL CASE
(For Organizational Defendants)

CASE NUMBER: 07-0140

LORIN REISNER AND JONATHAN TUTTLE
Defendant Organization's Attorney

THE DEFENDANT ORGANIZATION:

☑ pleaded guilty to count(s) one (1) and two (2) of the information filed in this case on May 30, 2007.

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

FILED
JUN 14 2007
NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

The organizational defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. 1001	FALSE STATEMENT	5/12/2006	1 and 2

The defendant organization is sentenced as provided in pages 2 through 8 of this judgment.

☐ The defendant organization has been found not guilty on count(s) _____

☑ Count(s) NONE ☐ is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant organization must notify the United States attorney for this district within 30 days of any change of name, principal business address, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant organization must notify the court and United States attorney of material changes in economic circumstances.

Defendant Organization's
Federal Employer I.D. No.. Unknown

Defendant Organization's Principal Business Address:

6/11/2007
Date of Imposition of Judgment

Ricardo M. Urbina
Signature of Judge

Ricardo M. Urbina — U.S. District Judge
Name of Judge — Title of Judge

6-14-07
Date

Defendant Organization's Mailing Address.

AO 245E (Rev. 12/03) Judgment in a Criminal Case for Organizational Defendants
Sheet 2 — Probation

DEFENDANT ORGANIZATION: BRYSTOL-MYERS SQUIBB COMPANY
CASE NUMBER: 07-0140

FINE

The defendant organization is hereby sentenced to a fine of :

ONE MILLION DOLLARS ($1,000,000.00) which shall be paid within 15 days after entry of judgment.

The defendant organization shall not commit another federal, state or local crime.

If this judgment imposes a fine or a restitution obligation, it is a condition of probation that the defendant organization pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant organization must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page (if indicated below).

STANDARD CONDITIONS OF SUPERVISION

1) within thirty days from the date of this judgment, the defendant organization shall designate an official of the organization to act as the organizations's representative and to be the primary contact with the probation officer;
2) the defendant organization shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
3) the defendant organization shall notify the probation officer ten days prior to any change in principal business or mailing address;
4) the defendant organization shall permit a probation officer to visit the organization at any of its operating business sites;
5) the defendant organization shall notify the probation officer within seventy-two hours of any criminal prosecution, major civil litigation, or administrative proceeding against the organization;
6) the defendant organization shall not dissolve, change its name, or change the name under which it does business unless this judgment and all criminal monetary penalties imposed by this court are either fully satisfied or are equally enforceable against the defendant's successors or assignees; and
7) the defendant organization shall not waste, nor without permission of the probation officer, sell, assign, or transfer its assets.

AO 245E (Rev. 12/03) Judgment in a Criminal Case for Organizational Defendants
Sheet 3 — Criminal Monetary Penalties

DEFENDANT ORGANIZATION: BRYSTOL-MYERS SQUIBB COMPANY
CASE NUMBER: 07-0140

CRIMINAL MONETARY PENALTIES

The defendant organization must pay the following total criminal monetary penalties under the schedule of payments on Sheet 4.

	Assessment	Fine	Restitution
TOTALS	$ 400.00	$ 1,000,000.00	$ 0.00

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant organization shall make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant organization makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
TOTALS	$ 0.00	$ 0.00	

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant organization shall pay interest on restitution or a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 4 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant organization does not have the ability to pay interest, and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

AO 245E (Rev. 12/03) Judgment in a Criminal Case for Organizational Defendants
Sheet 3A — Criminal Monetary Penalties

DEFENDANT ORGANIZATION: BRYSTOL-MYERS SQUIBB COMPANY
CASE NUMBER: 07-0140

ADDITIONAL TERMS FOR CRIMINAL MONETARY PENALTIES

The One Million Dollar ($1,000,000.00) fine shall be paid within 15 days after entry of judgment

AO 245E (Rev. 12/03) Judgment in a Criminal Case for Organizational Defendants
Sheet 4 — Schedule of Payments

DEFENDANT ORGANIZATION: BRYSTOL-MYERS SQUIBB COMPANY
CASE NUMBER: 07-0140

SCHEDULE OF PAYMENTS

Having assessed the organization's ability to pay, payment of the total criminal monetary penalties are due as follows:

A ☑ Lump sum payment of $ 400.00 due immediately, balance due

☐ not later than _____ , or
☐ in accordance with ☐ C or ☐ D below; or

B ☐ Payment to begin immediately (may be combined with ☐ C or ☐ D below); or

C ☐ Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

D ☑ Special instructions regarding the payment of criminal monetary penalties:

The $400.00 special assessment fee is due immediately and shall be paid to the Clerk of the Court for the U. S. District Court, District of Columbia.

The One Million Dollar ($1,000,000.00) fine shall be paid within 15 days after entry of judgment.

All criminal monetary penalties are made to the clerk of the court.

The defendant organization shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant organization shall pay the cost of prosecution.

☐ The defendant organization shall pay the following court cost(s):

☐ The defendant organization shall forfeit the defendant organization's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

EXHIBIT D

FILED
MAR 26 2009
Clerk, U.S. District and Bankruptcy Courts

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580
Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY
345 Park Avenue
New York, New York
Defendant.

CIVIL ACTION NO.

Case: 1:09-cv-00576
Assigned To : Sullivan, Emmet G.
Assign. Date : 3/26/2009
Description: General Civil

COMPLAINT FOR CIVIL PENALTIES PURSUANT TO
SECTION 5(*l*) OF THE FEDERAL TRADE COMMISSION ACT

Plaintiff, the Federal Trade Commission (the "Commission"), by its undersigned attorneys, alleges as follows:

JURISDICTION AND VENUE

1. This is an action under Section 5(*l*) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(*l*), for civil penalties against defendant Bristol-Myers Squibb Company ("BMS") for violations of a final order to cease and desist issued by the Federal Trade Commission and under Title XI, Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.Law 108-173, 117 Stat. 2461 (Dec. 8, 2003) ("MMA").

This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 45(*l*) and 28 U.S.C. §§ 1331, 1337 (a), 1345, and 1355.

2. Venue in this district is proper under 15 U.S.C. § 45(*l*) and 28 U.S.C. § 1391(b) and (c). Defendant transacts business in the District of Columbia.

3. BMS, at all times relevant to this proceeding, has been engaged in commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

THE PARTIES

4. The Commission is an administrative agency of the United States government established, organized, and existing pursuant to the FTC Act (15 U.S.C. §§ 41, *et seq.*), with its principal offices at 600 Pennsylvania Avenue, NW, Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act and is authorized under Section 5(*l*) of the FTC Act, 15 U.S.C. § 45(*l*), to initiate court proceedings to seek civil penalties for violations of Commission Orders and to secure such equitable relief as may be appropriate in each case.

5. BMS is a corporation organized and existing under the laws of Delaware with its principal place of business located at 345 Park Avenue, New York, NY 10154. BMS is, among other things, engaged in the discovery, development, manufacturing, and distribution of prescription pharmaceutical products (including Plavix®) in the United States.

SECTION 5(*l*) OF THE FTC ACT

6. Section 5(*l*) of the FTC Act, 15 U.S.C. § 45(*l*), provides:

> Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such order shall be a separate offense, except that in the case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.

7. Under Section 16 of the Federal Trade Commission Act, 15 U.S.C. § 56, the Commission is authorized to bring an action for civil penalties under Section 5(*l*) of the Federal Trade Commission Act.

8. Pursuant to the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, the maximum civil penalty for violations that occurred after November 19, 1996, but before February 9, 2009, is $11,000 per violation or for each day of a continuing violation.

THE MEDICARE MODERNIZATION ACT OF 2003

9. Section 1112(c) of the MMA requires each party to a settlement of patent litigation, i.e., agreements pursuant to Sections 1112(a) and 1112(b) of the MMA, to file such settlements with the FTC and the Department of Justice.

10. Section 1112(c)(3) requires that

> in the event that any agreement required to be filed under Section 1112(a) or (b) 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.

11. Section 1115 of the MMA provides:

> [a]ny brand name drug company or generic drug applicant which fails to comply with any provision of the subtitle shall be liable for a civil penalty of not more that $11,000, for each day during which such entity is in violation of the subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the [Federal Trade] Commission in accordance with the procedures established in section 16(a)(1) of the Federal TradeCommission Act (15 U.S.C. 56(a)).

THE COMMISSION'S ADMINISTRATIVE ACTION AGAINST BRISTOL-MYERS SQUIBB COMPANY

12. In a proceeding entitled *In the Matter of Bristol-Myers Squibb Company*, FTC Docket No. C-4076, 135 F.T.C. 444 (2003), the Commission issued an administrative complaint charging BMS with violating Section 5 of the FTC Act, 15 U.S.C. § 45. The administrative complaint alleged, *inter alia*, that BMS had entered into certain agreements in restraint of trade with regard to the market for buspirone products and paclitaxel-based drugs in the United States and engaged in certain acts and practices to monopolize the market for buspirone products, paclitaxel-based drugs, and Platinol in the United States.

13. The Commission's administrative complaint alleged, in part, that BMS engaged in an unfair method of competition in violation of Section 5 of the FTC Act, 15, U.S.C. § 45 by entering into a December 2, 1994, agreement with a would-be generic competitor, Schein Pharmaceuticals, Inc. ("Schein"), to pay Schein $72.5 million dollars to abandon its challenge of a BMS patent, and to refrain from competing with any generic bioequivalent version of that drug until patent expiry nearly six years later.

14. BMS waived its rights to contest any part of the Commission's administrative complaint, and entered into an Agreement Containing Consent Order. The Commission

accepted the Agreement on March 7, 2003, and placed it on the public record for receipt of comments.

15. On April 18, 2003, the Commission issued its final order in FTC Docket No. C-4076 ("Order"), 135 F.T.C. 486, with the consent of BMS. The Order was served upon BMS and became final on April 21, 2003. The Order has not at any time been modified or set aside, and is now and has been at all times since April 21, 2003, in full force and effect.

16. Paragraph XII of the Order provides, in part, that BMS is prohibited from entering into final settlements of patent litigation in which (1) it provides "something of value" to a potential generic entrant, and (2) the generic agrees not to sell its product for some period of time.

17. A proviso to Paragraph XII provides three exceptions to this prohibition. The second exception, which is relevant to this matter, provides that BMS can resolve or settle such litigation "after the Commission, in response to a request by Respondent BMS for an advisory opinion pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R.§ 1.2 ("Rule 1.2"), determines that the settlement agreement (defined in the Order to mean "anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1, or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45") would not raise issues under Section 5 of the FTC Act."

18. Rule 1.2 provides, in relevant part, that a request for advice shall "state all facts which the applicant believes to be material."

19. Paragraph XVI.C.1 of the Order provides, in part, that "representatives of the Commission may make a written request for additional information . . ." relevant to a request for advice made pursuant to Paragraph XII.

VIOLATIONS ALLEGED

FIRST COUNT

BMS Violated Paragraph XII of the Order by Concealing a Material Fact from the Settlement Agreement Submitted with the Request for an Advisory Opinion

20. Plaintiff realleges and incorporates by reference paragraphs 1 to 19, *supra*.

21. BMS co-developed and co-markets the branded drug Plavix® with Sanofi-Aventis ("Sanofi"), Europe's largest pharmaceutical company. Sanofi holds a composition-of-matter patent for Plavix® (patent no. 4,847,265, or the "'265 patent"), which it licenses exclusively to BMS. That patent is currently due to expire on November 17, 2011, and was the subject of the litigation with Apotex Inc. ("Apotex") that BMS was attempting to resolve.

22. On March 30, 2006, BMS submitted, pursuant to the second Paragraph XII proviso, a request for an advisory opinion concerning a proposed settlement agreement it had reached with Apotex, in the litigation over the validity of the '265 patent. The settlement agreement was attached to the request.

23. In its letter of submission, BMS stated that the attached settlement agreement also was being submitted as required by Section 1112(a) of the MMA.

24. On March 31, 2006, Apotex submitted a copy of the proposed settlement with BMS, as required pursuant to Section 1112(a) of the MMA.

25. In addition to Paragraph 4 of that settlement agreement, which granted Apotex a license under the '265 patent to sell the generic equivalent of Plavix® effective on September 17, 2011, Paragraph 5 of that agreement further provided that BMS would, during the first six

months of that license, agree not to launch, or authorize any other party to launch, a generic ("authorized generic") product.

26. Commission staff informed BMS that the promise not to launch an authorized generic in exchange for the Apotex's agreement to settle the patent litigation did raise issues under Section 5 of the FTC Act. The staff further informed BMS that such an agreement was specifically one that Paragraph XII of the Order sought to prevent and that the Commission was unlikely to issue an advisory opinion that the "Agreement would not raise issues under Section 5 of the Federal Trade Commission Act."

27. On May 18, 2006, BMS submitted a written request to withdraw its request for an advisory opinion concerning the proposed settlement agreement with Apotex.

28. On May 30, 2006, BMS submitted its second request for an advisory opinion concerning a revised proposed settlement with Apotex. That revised settlement agreement was attached to that request.

29. The May 30, 2006, submission noted also that the revised settlement agreement was being submitted as required pursuant to Section 1112(a) of the MMA.

30. As relevant to this matter, the most significant revision to the settlement agreement was the absence of BMS's promise not to launch an authorized generic during the first six months of Apotex's license.

31. On June 5, 2006, Apotex, also submitted the revised settlement agreement to the Commission, as required pursuant to Section 1112(a) of the MMA.

32. The cover letter accompanying the Apotex submission stated that BMS had made certain oral representations in addition to those included in the written settlement agreement being submitted.

33. Concerned that BMS had made an oral commitment to Apotex not to launch an authorized generic during the first six months of Apotex's license, on June 8, 2006, Commission staff, sent a letter to BMS asking it to certify and to declare under penalty of perjury that the revised settlement agreement set forth "the complete, final, and exclusive agreement," that it "superseded and canceled all prior and contemporaneous agreements" with regard to the settlement, and that "BMS had not made any representation, commitment, or promise to Apotex, whether oral or written," that was not 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."

34. On June 12, 2006, BMS submitted the requested certification.

35. On July 5, 2006, Apotex submitted additional exhibits, and a declaration confirming its position that BMS had made additional oral representations.

36. Presented with conflicting declarations, on July 20, 2006, the Commission opened a non-public investigation to determine which declaration was true.

37. Commission staff also notified the Department of Justice of the contradictory sworn declarations, and on July 28, 2006, the Department of Justice's Antitrust Division opened an investigation to determine whether the BMS and Apotex activities relating to their settlement agreement on Plavix® and their MMA submissions violated any criminal statutes.

38. On August 8, 2008, Apotex launched its generic version of Plavix®.

39. On August 31, 2006, the United States District Court for the Southern District of New York granted BMS's August 15, 2006, motion for a preliminary injunction to enjoin Apotex's infringement of the Plavix® patent.

40. On June 11, 2007, the Department of Justice filed its Information before the United States District Court for the District of Columbia.

41. Paragraph 20 of the Information stated:

> 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 [BMS] would not launch an authorized generic in the event that the parties reached a final revised settlement agreement.

42. Paragraph 21 of the Information further stated that "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."

43. Count One of the Information charged that BMS

> . . . 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.

44. On June 11, 2007, BMS appeared before the United States District Court for the District of Columbia and entered its plea of guilty with an allocution to two counts of making a false statement in violation of 18 U.S.C. § 1001.

45. BMS pled guilty to the Count I charge that it

> 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 in that Defendant failed to disclose certain information that was material to the FTC and, therefore, operated as an incomplete and false statement to the FTC, in violation of 18 U.S.C. § 1001.

46. In its allocution explaining the nature of the incomplete and false statement made to the FTC, BMS explained that

> . . .a former BMS senior executive made oral representations to Apotex for the purpose of causing Apotex to conclude that BMS would not launch an authorized generic in the event that the parties reached a final revised settlement agreement. These representations . . . were not disclosed to the FTC at the time of the filing of the final revised settlement agreement and subsequent certification. The failure to disclose this information to the FTC at the time of the filing of the final revised settlement agreement and certification operated as incomplete and, therefore, a false statements [sic] to the FTC.

47. BMS did not provide all facts material to its request for advice as required by Rule 1.2 and, therefore, required by the second proviso to Paragraph XII of the Order and therefore violated that provision of the Order.

48. BMS was in continuous violation of the second proviso to Paragraph XII of the Order from May 30, 2006, the date it submitted the revised settlement agreement with its request for an advisory opinion, until at least August 31, 2006, the date it obtained a preliminary injunction against Apotex.

SECOND COUNT

BMS Violated Section 1112(c)(3) of the MMA by Submitting the Revised Settlement Agreement As Its Agreement with Apotex

49. Plaintiff realleges and incorporates by reference paragraphs 1 to 46, *supra*.

50. The settlement agreement submitted with the request for an advisory opinion, pursuant to the second proviso to Paragraph XII of the Commission's Order, is the same settlement agreement BMS was required to file pursuant to Section 1112(a) of the MMA.

51. BMS concealed a material fact and made a false representation and failed to disclose information material to the filed settlement agreement.

52. The failure to reduce a material fact and information to writing, and filing an incomplete statement of the settlement was a violation of the Section 1112(c)(3) of the MMA, which requires that the parties "file written descriptions . . . that are sufficient to disclose all the terms and conditions of the agreement."

53. BMS was in continuous violation of Section 1112(c)(3) of the MMA from May 30, 2006, the date it submitted the revised settlement agreement required by Section 1112(a) of the MMA until at least August 31, 2006, the date it obtained a preliminary injunction against Apotex.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

1. That the Court adjudge and decree that Defendant BMS's concealment of a material fact and its materially false, fictitious, and fraudulent statement concerning the settlement agreement filed in connection with its request for an advisory opinion required by the Order violated the Order and that Defendant BMS violated the Order each day of the period beginning on or about from May 30, 2006, until at least on or about August 31, 2006;

2. That the Court adjudge and decree that Defendant BMS's concealment of a material fact and its materially false, fictitious, and fraudulent statement concerning the settlement agreement filed as required by the MMA violated the MMA and that Defendant BMS violated the MMA each day of the period beginning on or about May 30, 2006, until at least on or about August 31, 2006;

3. That Defendant BMS be ordered to pay to the United States an appropriate civil penalty as provided by Section 5(*l*) of the FTC Act, 15 U.S.C. § 45(*l*), and the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, and Section 1115 of the MMA;

4. That Plaintiff have such other and further relief as the Court may deem just and proper; and

5. That Plaintiff be awarded its costs of this suit.

Dated: March 26, 2009

FOR THE FEDERAL TRADE COMMISSION:

David C. Shonka
Acting General Counsel

David P. Wales
Acting Director
Bureau of Competition
D.C. Bar #456894

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Ellen Connelly
Kenneth A. Libby
Attorneys for Plaintiff

By: _____

Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

E
09-576
EGS

CIVIL COVER SHEET

JS-44
(Rev.1/05 DC)

I (a) PLAINTIFFS

Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C..20580

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Kenneth A. Libby, Anne R. Schenof, Daniel P. Ducore
Federal Trade Commission
601 New Jersey Ave., N.W. 20580
202-326-2526

DEFENDANTS

Bristol-Myers Squibb Company
345 Park Ave.
New York, N.Y. 10154

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT
(IN U.S. PLAINTIFF CASES ONLY) 88888
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF

Case: 1:09-cv-00576
Assigned To : Sullivan, Emmet G.
Assign. Date : 3/26/2009
Description: General Civil

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- (●) 1 U.S. Government Plaintiff
- ( ) 2 U.S. Government Defendant
- ( ) 3 Federal Question (U.S. Government Not a Party)
- ( ) 4 Diversity (Indicate Citizenship of Parties in item III)

III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	( ) 1	( ) 1	Incorporated or Principal Place of Business in This State	( ) 4	( ) 4
Citizen of Another State	( ) 2	( ) 2	Incorporated and Principal Place of Business in Another State	( ) 5	(●) 5
Citizen or Subject of a Foreign Country	( ) 3	( ) 3	Foreign Nation	( ) 6	( ) 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

( ) A. *Antitrust*

- [ ] 410 Antitrust

( ) B. *Personal Injury/ Malpractice*

- [ ] 310 Airplane
- [ ] 315 Airplane Product Liability
- [ ] 320 Assault, Libel & Slander
- [ ] 330 Federal Employers Liability
- [ ] 340 Marine
- [ ] 345 Marine Product Liability
- [ ] 350 Motor Vehicle
- [ ] 355 Motor Vehicle Product Liability
- [ ] 360 Other Personal Injury
- [ ] 362 Medical Malpractice
- [ ] 365 Product Liability
- [ ] 368 Asbestos Product Liability

( ) C. *Administrative Agency Review*

- [ ] 151 Medicare Act

Social Security:
- [ ] 861 HIA ((1395ff)
- [ ] 862 Black Lung (923)
- [ ] 863 DIWC/DIWW (405(g)
- [ ] 864 SSID Title XVI
- [ ] 865 RSI (405(g)

Other Statutes
- [ ] 891 Agricultural Acts
- [ ] 892 Economic Stabilization Act
- [ ] 893 Environmental Matters
- [ ] 894 Energy Allocation Act
- [ ] 890 Other Statutory Actions (If Administrative Agency is Involved)

( ) D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

(●) E. *General Civil (Other)* OR **( ) F. *Pro Se General Civil***

Real Property
- [ ] 210 Land Condemnation
- [ ] 220 Foreclosure
- [ ] 230 Rent, Lease & Ejectment
- [ ] 240 Torts to Land
- [ ] 245 Tort Product Liability
- [ ] 290 All Other Real Property

Personal Property
- [ ] 370 Other Fraud
- [ ] 371 Truth in Lending
- [ ] 380 Other Personal Property Damage
- [ ] 385 Property Damage Product Liability

Bankruptcy
- [ ] 422 Appeal 28 USC 158
- [ ] 423 Withdrawal 28 USC 157

Prisoner Petitions
- [ ] 535 Death Penalty
- [ ] 540 Mandamus & Other
- [ ] 550 Civil Rights
- [ ] 555 Prison Condition

Property Rights
- [ ] 820 Copyrights
- [ ] 830 Patent
- [ ] 840 Trademark

Federal Tax Suits
- [ ] 870 Taxes (US plaintiff or defendant
- [ ] 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- [ ] 610 Agriculture
- [ ] 620 Other Food &Drug
- [ ] 625 Drug Related Seizure of Property 21 USC 881
- [ ] 630 Liquor Laws
- [ ] 640 RR & Truck
- [ ] 650 Airline Regs
- [ ] 660 Occupational Safety/Health
- [X] 690 Other

Other Statutes
- [ ] 400 State Reapportionment
- [ ] 430 Banks & Banking
- [ ] 450 Commerce/ICC Rates/etc.
- [ ] 460 Deportation
- [ ] 470 Racketeer Influenced & Corrupt Organizations
- [ ] 480 Consumer Credit
- [ ] 490 Cable/Satellite TV
- [ ] 810 Selective Service
- [ ] 850 Securities/Commodities/ Exchange
- [ ] 875 Customer Challenge 12 USC 3410
- [ ] 900 Appeal of fee determination under equal access to Justice
- [ ] 950 Constitutionality of State Statutes
- [ ] 890 Other Statutory Actions (if not administrative agency review or Privacy Act

O G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus-General ☐ 510 Motion/Vacate Sentence	O H. *Employment Discrimination* ☐ 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	O I. *FOIA/PRIVACY ACT* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	O J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loans (excluding veterans)
O K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 730 Labor/Mgmt. Reporting & Disclosure Act ☐ 740 Labor Railway Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	O L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 444 Welfare ☐ 440 Other Civil Rights ☐ 445 American w/Disabilities-Employment ☐ 446 Americans w/Disabilities-Other	O M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	O N. *Three-Judge Court* ☐ 441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN
(•) 1 Original Proceeding O 2 Removed from State Court O 3 Remanded from Appellate Court O 4 Reinstated or Reopened O 5 Transferred from another district (specify) O 6 Multi district Litigation O 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
15 U.S.C. sec 45(l); and Pub. Law 108-173, 117 Stat. 2461. Action for civil penalties for violation of final agency order, and of Medicare Modern. Act

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ $2,100,000.00 Check YES only if demanded in complaint
JURY DEMAND: YES ☐ NO [X]

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO [X] If yes, please complete related case form.

DATE March 26, 2009 SIGNATURE OF ATTORNEY OF RECORD [signature]

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff is resident of Washington, D.C.; 88888 if plaintiff is resident of the United States but not of Washington, D.C., and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of case.

VI. CAUSE OF ACTION: Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASES, IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

KB

FILED
MAR 26 2009
Clerk, U.S. District and Bankruptcy Courts

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY,

Defendant.

Case: 1:09-cv-00576
Assigned To : Sullivan, Emmet G.
Assign. Date : 3/26/2009
Description: General Civil

STIPULATION

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

(1) the parties consent that the Court may file and enter a Final Judgment in the form attached to this Stipulation, on the Court's own motion or on the motion of any party at any time, and without further notice to any party or other proceedings, if Plaintiff has not withdrawn its consent, which it may do at any time before the entry of judgment by serving notice of its withdrawal on Defendant Bristol-Myers Squibb Company and filing that notice with the Court;

(2) the parties have entered into this Stipulation to settle in full all claims related to Bristol-Myers Squibb Company's alleged failure, with its May 30, 2006, filing of a settlement agreement with Apotex Inc., to comply with Paragraph XII of the final order issued by the Commission in FTC Docket C-4076, and to settle in full all claims related to Bristol-Myers Squibb Company's alleged failure, with its May 30, 2006, filing of a settlement agreement with Apotex Inc., to comply with Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.Law 108-173 Stat. 2461 (Dec. 8, 2003).

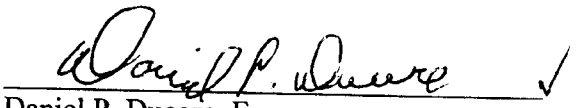
(3) This Stipulation is for settlement purposes only and does not constitute an admission by Bristol-Myers Squibb Company that the law has been violated as alleged or that any of the facts alleged, other than jurisdictional facts, are true.

(4) Defendant Bristol-Myers Squibb Company waives any objection to venue or jurisdiction for purposes of the Final Judgment and authorizes Lorin L. Reisner, Esq. of Debevoise & Plimpton LLP to accept service of all process in this matter on its behalf; and

(5) In the event Plaintiff withdraws its consent or, if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

(6) Plaintiff considers entry of the Final Judgment to be in the Public Interest.

Dated: March 26, 2009
FOR THE FEDERAL TRADE COMMISSION:
By:



Daniel P. Ducore, Esq.
D.C Bar No. 933721
Assistant Director
Anne R. Schenof, Esq.
D.C. Bar No. 185462
Kenneth A. Libby
Attorneys
Federal Trade Commission
Washington, D.C. 20580
(202) 326-2526

David P. Wales
Acting Director
Marian Bruno
Deputy Director
Bureau of Competition

Dated: March 11, 2009
Bristol-Myers Squibb Company
a Delaware corporation
By:

General Counsel

Lorin L. Reisner, Esq.
Debevoise & Plimpton LLP

DEBEVOISE & PLIMPTON LLP

919 Third Avenue
New York, NY 10022
Tel 212 909 6000
www.debevoise.com

Lorin L. Reisner
Partner
Tel 212 909 6191
Fax 212 909 6836
llreisner@debevoise.com

March 25, 2009

BY FEDERAL EXPRESS

Daniel P. Ducore, Esq.
Assistant Director
Federal Trade Commission
Bureau of Competition
601 New Jersey Avenue, N.W., Suite 5223
Washington, D.C. 20001

Federal Trade Commission v. Bristol-Myers Squibb Company

Dear Mr. Ducore:

By this letter, counsel for Bristol-Myers Squibb Company agree and stipulate that the parties and the Court may consider the telefaxed signature pages of March 11, 2009, as true and original signatures of defendant for all purposes relating to the matter.

Very truly yours,

Lorin L. Reisner/SLA

Lorin L. Reisner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED
MAR 26 2009
Clerk, U.S. District and Bankruptcy Courts

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580
Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY
345 Park Avenue
New York, New York
Defendant.

CIVIL ACTION NO.

Case: 1:09-cv-00576
Assigned To : Sullivan, Emmet G.
Assign. Date : 3/26/2009
Description: General Civil

PLAINTIFF'S MOTION FOR ENTRY OF FINAL JUDGMENT

Plaintiff Federal Trade Commission, having filed its Complaint in the above-captioned case, and having filed on this date a Stipulation and proposed Final Judgment, hereby moves this Court for entry of a Final Judgment against defendant Bristol-Myers Squibb Company ("BMS"). By agreement of the parties, the Final Judgment provides for the payment of civil penalties totaling $2,100,000 by defendant pursuant to section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45 (l), and section 1115 of Title XI, Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173, 117 Stat. 2461 (Dec. 8, 2003)("MMA").

STATEMENT OF POINTS AND AUTHORITIES

The Complaint in this action alleges that the defendant violated a final order of the Federal Trade Commission in FTC Docket No. C-4076 ("Order"), and also violated the provisions of the MMA. The Complaint alleges that BMS filed a certain "settlement agreement" pursuant to the Order and as required by the MMA but failed to disclose certain material facts regarding certain additional understandings that BMS had with the other party to the settlement agreement, Apotex, Inc. The Complaint further alleges that defendant BMS was in violation of the Order and the MMA from at least May 30, 2006, when it filed the settlement agreement, to at least August 31, 2006.

Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), provides that

> Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such order shall be a separate offense, except that in the case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.

Pursuant to the Debt Collection Improvement Act of 1996, Pub. L. 104-134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, the maximum civil penalty for violations that occurred after November 19, 1996, but before February 9, 2009, is $11,000 per violation or for each day of a continuing violation.

Section 1115(a) of the MMA provides,

> Any brand name drug company or generic drug applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15. U.S.C. 56(a)).

As the Stipulation and proposed Final Judgment state, the defendants has agreed to pay a civil penalties of $2,100,000 within thirty days of entry of the Final Judgment.

For the above reasons, the Federal Trade Commission asks the Court to enter the Final Judgment in this case.

Dated: March 26, 2009
FOR THE FEDERAL TRADE COMMISSION:

David C. Shonka
Acting General Counsel

David P. Wales
Acting Director
Bureau of Competition
D.C. Bar #456894

Daniel P. Ducore
Assistant Director
D.C. Bar # 933721

Anne R. Schenof
D.C. Bar # 185454
Ellen Connelly

Kenneth A. Libby
D.C. Bar #
Attorneys for Plaintiff

By: /Daniel P. Ducore/
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

CERTIFICATE OF SERVICE

I hereby certify that on the 16th day of March 2009, I caused a copy of the foregoing Motion of Plaintiff United States For Entry of Final Judgment to be mailed, by U.S. mail, postage prepaid, to the attorneys listed below.

Daniel P. Ducore

Daniel P. Ducore

For Bristol-Myers Squibb Company:

Lorin L. Reisner, Esq.
Debevoise & Plimpton LLP
919 Third Avenue
New York, New York 10022

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, Defendant.	)	Civ. No. 09 0576

FINAL JUDGMENT

Plaintiff, Federal Trade Commission, having commenced this civil action by filing its Complaint herein for alleged violations of an Order issued by the Federal Trade Commission on April 14, 2003, in FTC Docket No. C-4076 (the "Order") and for alleged violations of Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173 Stat. 2461 (Dec. 8, 2003), and Defendant, Bristol-Myers Squibb Company ("BMS"), having agreed to the entry of this Final Judgment in settlement of disputed claims without trial or adjudication of any issue of fact or law herein and without any admission by Defendant as to the facts alleged, other than jurisdictional facts:

NOW, THEREFORE, prior to the taking of any testimony, civil discovery, and without trial or adjudication of any issue of fact or of law herein, and upon the consent of the parties hereto, it is hereby

ORDERED, ADJUDGED, AND DECREED as follows:

I.

This Court has jurisdiction of the subject matter herein and of each of the parties consenting hereto. The Complaint asserts a claim upon which relief can be granted against Defendant under Sections 5(l) and 16(a)(1) of the Federal Trade Commission Act, 15 U.S.C. §§ 45(l) and 56(a)(1), and the Complaint asserts a claim upon which relief can be granted against Defendant under Section 1115 of Title XI, Subtitle B of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173 Stat. 2461 (Dec. 8 2003) and Section 16(a)(1) of the Federal Trade Commission Act, 15 U.S.C. § 56(a)(1).

II.

Judgment is hereby entered in favor of the Plaintiff, Federal Trade Commission, and against the Defendant as alleged in the Complaint in this action. Defendant shall comply with the provisions of this Final Judgment.

III.

Defendant shall pay to the United States a civil penalty in the amount of two million and one hundred thousand United States dollars ($2,100,000.00), which shall be paid and delivered in the following manner:

A. Payment shall be made within thirty (30) days after entry of this Final Judgment;

B. Payment shall be made by wire transfer of funds to the US Federal Trade Commission pursuant to instructions provided by Plaintiff; and

C. In the event of a default or delay in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of the default or delay to the date of payment.

IV.

Each party shall bear its own costs of the within action.

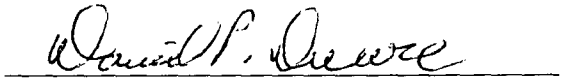
V.

Entry of this Final Judgment is in the public interest.

VI.

By their attached signatures hereto, the parties agree to the entry of this Final Judgment.

FEDERAL TRADE
COMMISSION
By:



Daniel P. Ducore, Esq.
D.C. Bar No. 933721
Assistant Director
Anne R. Schenof, Esq.
D.C. Bar No. 185462
Kenneth A. Libby
Attorneys
Federal Trade Commission
Washington, D.C. 20580
(202) 326-2526

David P. Wales
Acting Director
Marian Bruno
Deputy Director
Bureau of Competition

Bristol-Myers Squibb Company,
a Delaware corporation
By:

General Counsel

Lorin L. Reisner, Esq.
Debevoise & Plimpton LLP

Dated: 3/30/, 2009

United States District Judge

JS 44 (Rev. 2/08) **CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS
Apotex Pharmaceutical Holdings. Inc., a Canadian corporation and APOTEX CORP., a Delaware corporation

(b) County of Residence of First Listed Plaintiff BROWARD
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Lida Rodriguez-Taseff, Esq.
Duane Morris LLP,200 S. Biscayne Blvd., Ste. 3400, Miami, FL 33131

DEFENDANTS
Sanofi-Aventis, a corporation of France, Sanofi-Synthelabo, Inc., a Delaware corporation, Bristol-Myers Squibb Company, a Delaware corporation and Bristol-Myers Squibb Sanofi-Pharmaceuticals Holding Partnership, a Delaware corporation

County of Residence of First Listed Defendant FRANCE
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED.

Attorneys (If Known)

0:09CV 61575-Cohn-Seltzer

(d) Check County Where Action Arose: ☐ MIAMI- DADE ☐ MONROE ☒ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST.LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury -Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☒ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	SOCIAL SECURITY	☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	☐ 861 HIA (1395ff)	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 862 Black Lung (923)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 863 DIWC/DIWW (405(g))	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	FEDERAL TAX SUITS	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	**Habeas Corpus:**	☐ 791 Empl. Ret. Inc. Security Act	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General	IMMIGRATION	☐ 871 IRS—Third Party 26 USC 7609	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty	☐ 462 Naturalization Application		☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities – Employment	☐ 540 Mandamus & Other	☐ 463 Habeas Corpus - Alien Detainee		☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities – Other	☐ 550 Civil Rights	☐ 465 Other Immigration Actions		☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed- **(see VI below)** ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. RELATED/RE-FILED CASE(S). (See instructions second page): a) Re-filed Case ☐ YES ☒ NO JUDGE b) Related Cases ☐ YES ☒ NO DOCKET NUMBER

VII. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause **(Do not cite jurisdictional statutes unless diversity):** 35 USC §271, et seq. and 28 USC §§1331, 1338, 2201-2202

LENGTH OF TRIAL via 1+03 days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A ~~CLASS~~ ACTION UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE SIGNATURE OF ATTORNEY OF RECORD DATE Oct. 2 2009

FOR OFFICE USE ONLY
AMOUT 350 RECEIPT # 547698 IFP