

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

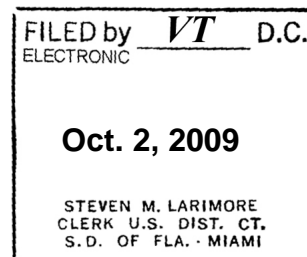
APOTEX PHARMACEUTICAL HOLDINGS,
INC., a Canadian corporation and APOTEX
CORP., a Delaware corporation,

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

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.

_____ /

**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 Court.

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

DUANE MORRIS LLP

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Florida Bar No. 145928
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