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 Trade Commission 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

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