IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. APOTEX, INC. and APOTEX CORP., Defendants.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Bristol-Myers Squibb Company ("BMS"), by its undersigned attorneys, for its Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively "Defendants" or "Apotex"), hereby alleges as follows:

Nature of Action

1. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code.

The Parties

2. Plaintiff BMS is a corporation organized and existing under the laws of the State of Delaware having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

3. Upon information and belief, Apotex, Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

4. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex, Inc. Upon information and belief, Apotex Corp. acts at the direction of, under the control of, and at least in part for the direct benefit of Apotex, Inc. and is controlled and/or dominated by Apotex, Inc. Upon information and belief, the acts of Apotex Corp. complained of herein were done at the direction of and with the authorization, cooperation, participation, and assistance of Apotex, Inc.

6. Upon information and belief, Apotex Corp. serves as Apotex Inc.'s United States sales agent and distributor and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in the District of Delaware.

7. Upon information and belief, Apotex Corp. is an agent, affiliate, or subsidiary of Apotex, Inc., including for Abbreviated New Drug Application ("ANDA") No. 203033 ("the Apotex ANDA").

Jurisdiction and Venue

8. This action arises under the Patent Laws of the United States, Title 35 of the United States Code. This Court therefore has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over both of the Defendants, Apotex, Inc. and Apotex Corp.

10. Apotex Corp. is incorporated in Delaware and therefore subject to the jurisdiction of this Court. As a domestic corporation, Apotex Corp. is registered to do business with the

Delaware Department of State Division of Corporations. Furthermore, Apotex Corp. markets and sells generic drugs within the state of Delaware and throughout the United States.

11. Upon information and belief, Apotex Corp. avails itself of the benefits and protections of the laws of the state of Delaware. For example, upon information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy pursuant to 24 *Del. C.* § 2540.

12. Upon information and belief, Apotex Corp. has operated as an instrumentality of Apotex Inc. in relation to the preparation and submission of the Apotex ANDA, which seeks approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of a generic version of BMS's patent-protected drug Baraclude®.

13. Upon information and belief, Apotex, Inc. is the applicant of record for the Apotex ANDA, which was filed with the U.S. Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to manufacture, use, sell, offer for sale, and/or import in the United States a 0.5 mg and 1 mg dosage strength entecavir drug product in the form of tablets for oral administration.

14. Upon information and belief, Apotex, Inc. resides and is doing business within this judicial district through its agent, Apotex Corp.

15. Upon information and belief, Apotex, Inc. has a continuous and systematic business presence within this judicial district and/or substantial events giving rise to acts of infringement that have occurred and/or will occur within this judicial district including its preparation of and/or contribution to the submission and/or filing of the Apotex ANDA seeking approval to sell or offer to sell Apotex's generic drug products in the United States, including the state of Delaware.

16. In the alternative, and to the extent that Apotex, Inc. is not subject to the jurisdiction of this Court as a resident of Delaware, it is subject to the jurisdiction of the Court pursuant to 10 *Del. C.* § 3104. Specifically, Apotex, Inc. causes tortious injury in Delaware, namely from the tort of patent infringement, and Apotex regularly does or solicits business, engages in a persistent course of conduct in Delaware and this District, and derives substantial revenue from things used or consumed in Delaware and this District.

17. Upon information and belief, Apotex, Inc.'s business includes developing, manufacturing, distributing, and/or selling generic drug products for sale and use throughout the United States including for sale and use in the state of Delaware.

18. Upon information and belief, Apotex, Inc. has derived revenue from generic drug products distributed and/or sold in the state of Delaware.

19. Upon information and belief, Apotex, Inc. has previously submitted to the jurisdiction of this Court and has previously availed itself of the benefits and protections of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *In re Armodafinil Patent Lit*., 939 F. Supp. 2d 456 (D. Del. 2013); *Apotex, Inc. v. Senju Pharm. Co. Ltd.*, 921 F. Supp. 2d 308 (D. Del. 2013).

20. Venue is proper in this District under 28 U.S.C. § 1391(b), (c) and 28 U.S.C. § 1400(b).

Background

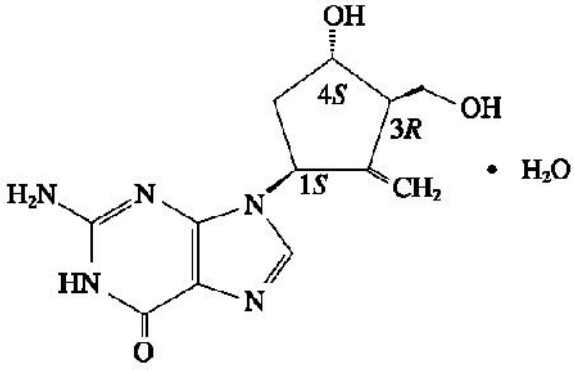
21. BMS is the holder of New Drug Application ("NDA") No. 21-797, which relates to tablets containing 0.5 mg and 1 mg of entecavir. On March 29, 2005, the United States Food and Drug Administration ("FDA") approved the marketing of the tablets described in NDA No. 21-797 for the treatment of chronic hepatitis B virus infection in adults with evidence of active

viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. These tablets are prescribed and sold in the United States using the trademark Baraclude®.

22. United States Patent No 5,206,244 (the "'244 Patent," a true and accurate copy of which is attached hereto as Exhibit A), entitled "Hydroxymethyl (Methylenecyclopentyl) Purines and Pyrimidines," was duly and legally issued by the United States Patent and Trademark Office on April 27, 1993. The '244 patent claims, among other things, entecavir (the active ingredient in Baraclude®) and is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book") entry for Baraclude®.

23. BMS is the assignee of all rights in the '244 Patent.

24. Entecavir is a compound that has a molecular formula of $C_{12}H_{15}N_5O_3 \cdot H_2O$ and has the following chemical structure:



25. Entecavir can be referred to by any of several chemical names, but the described molecules are the same. The chemical name given to entecavir in the Baraclude® label is "2-amino-1,9-dihydro-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6H-purin-6-one, monohydrate." The chemical name recited for entecavir in the '244 patent is "[1S-(1α,3α,4β)]-2-Amino-1,9-dihydro-9-[4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6H-purin-6-one."

26. The named inventors on the ‘244 Patent are Robert Zahler and William A. Slusarchyk.

27. Robert Zahler and William A. Slusarchyk assigned the ‘244 Patent to E.R. Squibb & Sons, Inc. on September 13, 1991.

28. On September 8, 2004, the ‘244 patent was assigned to BMS.

COUNT 1
Infringement of U.S. Patent No. 5,206,244 (ANDA No. 203033)

29. BMS repeats and realleges paragraphs 1-28 above as if set forth herein.

30. Apotex submitted or caused to be submitted Abbreviated New Drug Application (“ANDA”) No. 203033 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of tablets containing 0.5 mg and 1 mg of entecavir (the “Apotex Formulation”).

31. Upon information and belief, ANDA No. 203033 seeks approval to market the Apotex Formulation for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

32. By letter dated February 7, 2014 (the “Notice Letter”) and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Apotex notified BMS that it had submitted ANDA No. 203033 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Apotex Formulation prior to the expiration of the ‘244 Patent.

33. BMS did not receive the Notice Letter until at least February 8, 2014.

34. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Apotex notified BMS by means of the Notice Letter that Apotex believed the ‘244 Patent to be “invalid, unenforceable, or not infringed.” This statutory section requires, *inter alia*, certification by the ANDA applicant that,

in its opinion and to the best of its knowledge, the subject patent (i.e., '244 Patent) "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." This statute also requires that a so-called Paragraph IV notice letter "include[s] a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." FDA Regulation 21 C.F.R. § 3111.95(c)(6)(ii)) further requires that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

35. Apotex alleged in its Notice Letter that claims 1-6, 8, and 10-11 of the '244 Patent are invalid, and that "the Apotex Formulation does not directly or indirectly infringe claims 7 and 9 of the '244 patent."

36. Apotex did not assert in its Notice Letter that claims 1-6, 8, or 10-11 of the '244 Patent are not infringed. Upon information and belief, Apotex does not deny that the filing of ANDA No. 203033 constitutes an act of infringement of claims 1-6, 8, or 10-11 of the '244 Patent to the extent that claims are not invalid or unenforceable. Upon information and belief, Apotex does not deny that the commercial manufacture, use, offer for sale, or sale in the United States of the Apotex Formulation and importation of the Apotex Formulation into the United States would constitute an act of infringement of claims 1-6, 8, or 10-11 of the '244 Patent to the extent that claims are not invalid or unenforceable.

37. By filing ANDA No. 203033 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of the Apotex Formulation before the '244 Patent's expiration, Apotex has committed an act of infringement of the '244 Patent under 35 U.S.C. § 271(e)(2).

38. Upon information and belief, the commercial manufacture, use, offer for sale, and sale in the United States of the Apotex Formulation and importation of the Apotex Formulation into the United States will infringe, induce infringement and/or contributorily infringe one or more claims of the '244 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff BMS respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Apotex's ANDA No. 203033 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date that is not earlier than the expiration of the '244 Patent or any later date of exclusivity to which Plaintiff is or becomes entitled;

(b) A judgment declaring that the '244 Patent is not invalid or unenforceable and has been infringed by Apotex;

(c) A permanent injunction against any infringement of the '244 Patent by Apotex, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(d) Costs and expenses in this action; and

(e) Such other relief as this Court may deem proper.

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Dated: March 19, 2014

/s/ Chad S.C. Stover

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