IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Bristol-Myers Squibb Company ("BMS"), for its Complaint against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva"), 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. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware having a place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090.

4. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Industries") is a company organized and existing under the laws of the Nation of Israel having a place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.

5. Teva USA is a wholly-owned subsidiary of Teva Industries. On information and belief, Teva USA shares officers and directors in common with Teva Industries.

6. On information and belief, the acts of Teva USA complained of herein were done at the direction of and with the authorization, cooperation, participation, and assistance of Teva Industries. On information and belief, the acts of Teva USA complained of herein were done at least in part for the benefit of Teva Industries.

Jurisdiction and Venue

7. 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).

8. This Court has jurisdiction over the person of Teva USA because Teva USA is incorporated in Delaware and therefore subject to the jurisdiction of this Court. As a domestic corporation, Teva USA is registered to do business with the Delaware Department of State, Division of Corporations. Additionally, Corporate Creations Network Inc., 3411 Silverside Road, Rodney Building #104, Wilmington, Delaware 19810 is authorized to accept service on behalf of Teva USA.

9. In the alternative, and to the extent that Teva 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, Teva causes tortious injury in Delaware, namely from the tort of patent infringement, and Teva 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.

10. On information and belief, Teva Industries manufactures and distributes bulk pharmaceuticals and pharmaceutical products that are sold by Teva USA (and others) throughout the United States, including in Delaware and this District.

11. Teva has availed itself of the benefits and protections of Delaware courts, including this one. Such cases include *Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, 07-cv-332-GMS and *Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, 07-cv-024-JJF.

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

Background

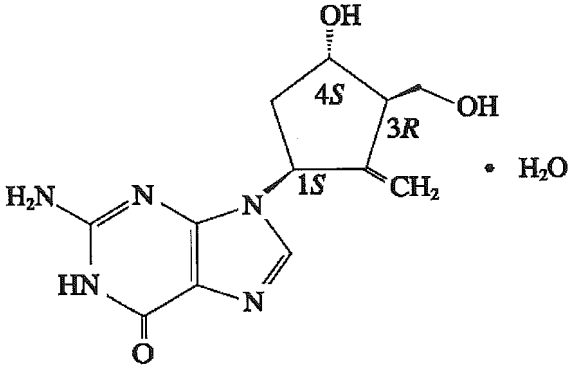
13. BMS is the holder of New Drug Application ("NDA") No. 21-797, which relates to tablets containing 0.5 mg and 1 mg of entecavir. On March 29, 2005, the United States Food and Drug Administration ("FDA") approved the marketing of the tablets described in NDA No. 21-797 for the treatment of chronic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

14. 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®.

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

16. 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:



17. 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."

18. The named inventors on the '244 Patent are Robert Zahler and William A. Slusarchyk.

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

20. On September 8, 2004, the '244 patent was assigned to BMS.

COUNT 1
Infringement of U.S. Patent No. 5,206,244 (ANDA No. 202122)

21. BMS repeats and realleges paragraphs 1-20 above as if set forth herein.

22. Teva submitted or caused to be submitted Abbreviated New Drug Application ("ANDA") No. 202122 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 ("Teva's Entecavir Tablets").

23. On information and belief, ANDA No. 202122 seeks approval to market Teva's Entecavir Tablets 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.

24. By letter dated August 11, 2010 (the "Notice Letter") and pursuant to 21 U.S.C. § 355(J)(2)(B)(ii), Teva notified BMS that it had submitted ANDA No. 202122 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's Entecavir Tablets prior to the expiration of the '244 Patent.

25. BMS did not receive the Notice Letter until at least August 12, 2010.

26. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Teva notified BMS by means of the Notice Letter that Teva 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."

27. Teva alleged in its Notice Letter that claims 1-6 and 8 of the '244 Patent are invalid, that "claims 7 and 9 are not infringed by Teva's Entecavir Tablets," that "Teva will not directly infringe claim 10 or 11 because Teva, as a pharmaceutical company, will not directly treat patients with Teva's Entecavir Tablets," and that "Teva's manufacture, use or sale of Teva's Entecavir Tablets would not induce infringement of or contribute to infringement of claims 10 and 11."

28. Teva did not assert in its Notice Letter that claims 1-6 or 8 of the '244 Patent are not infringed. On information and belief, Teva does not deny that the filing of ANDA No. 202122 constitutes an act of infringement of claims 1-6 and 8 of the '244 Patent to the extent that claims are not found invalid or unenforceable. On information and belief, Teva does not deny that the commercial manufacture, use, offer for sale, or sale in the United States of Teva's Entecavir Tablets and importation of Teva's Entecavir Tablets into the United States would constitute an act of infringement of claims 1-6 and 8 of the '244 Patent to the extent that claims are not found invalid or unenforceable.

29. By filing ANDA No. 202122 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Teva's Entecavir Tablets before the '244 Patent's expiration, Teva has committed an act of infringement of the '244 Patent under 35 U.S.C. § 271(e)(2).

30. On information and belief, the commercial manufacture, use, offer for sale, and sale in the United States of Teva's Entecavir Tablets and importation of Teva's Entecavir Tablets

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 Teva's ANDA No. 202122 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 remains valid and enforceable and has been infringed by Teva;

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

(d) A judgment that this is an exceptional case and that BMS is entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) Costs and expenses in this action; and

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

Dated: September 22, 2010

/s/ Jeffrey B. Bove

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