

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BRISTOL-MYERS SQUIBB COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
SANDOZ INC.,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Bristol-Myers Squibb Company (“BMS”), for its Complaint against Defendant Sandoz Inc. (“Sandoz”), 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. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado having a principle place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. On information and belief, Sandoz manufactures and distributes bulk pharmaceuticals and pharmaceutical products that are sold by Sandoz (and others) in Delaware and this District, and throughout the United States.

### **Jurisdiction and Venue**

4. 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).

5. Sandoz is subject to personal jurisdiction in this District by virtue of its presence and activities in the State of Delaware, and having maintained systematic and continuous contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

6. Sandoz is registered to distribute drugs in the State of Delaware, and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

7. Sandoz is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed “Distributor/Manufacturer CSR” (License No. DS0131) and “Pharmacy-Wholesale” (License No. A4-0000260). Sandoz admitted as much in its Answer in Cephalon v. Sandoz, 1:12-cv-00248-SLR (D. Del. Mar. 3, 2012).

8. Sandoz does business in the State of Delaware. Sandoz admitted as much in its Answer in Wyeth v. Sandoz, 1:08-cv-00317-JJF (D. Del. July 24, 2008).

9. Sandoz has entered into contracts with and/or purchased goods or services from companies located in Delaware, including at least Agilent Technologies, Inc., and LabWare, Inc. Sandoz admitted as much in its Answer in Cephalon v. Sandoz, 1:12-cv-00248-SLR (D. Del. Mar. 3, 2012).

10. Sandoz has regularly and recently employed Delaware counsel, such as in Valeant v. Sandoz, 1:12-cv-00536-SRF; Cephalon v. Sandoz, 1:12-cv-00248-SLR; Abbott v. Sandoz, 1:12-cv-00103-SLR; GlaxoSmithKline v. Sandoz, 1:11-cv-01284-RGA.

11. Personal jurisdiction over Sandoz is also proper because Sandoz committed the tort of patent infringement in this District pursuant to 35 U.S.C. § 271(e)(2)(A) by filing Abbreviated New Drug Application (“ANDA”) No. 203905 and is therefore subject to the jurisdiction of this Court pursuant to 10 Del. C. § 3104.

12. Additionally, personal jurisdiction over Sandoz is proper because it has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits pending in this Court.

13. Sandoz admitted or consented to jurisdiction (for purposes of litigation) and filed counterclaims in, for example, Cephalon v. Sandoz, 1:12-cv-00248-SLR (Mar. 23, 2012); Abbott v. Sandoz, 1:12-cv-00103-SLR (Apr. 9, 2012); GlaxoSmithKline v. Sandoz, 1:11-cv-01284-RGA (Mar. 5, 2012); Pfizer v. Sandoz, 1:11-cv-01252-GMS-MPT (Mar. 8, 2012).

14. Upon information and belief, Sandoz was and/or is registered as a foreign corporation with the Secretary of State of Delaware under 8 Del. C. § 371 in order to maintain at least the above counterclaims under 8 Del. C. § 371.

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

### **Background**

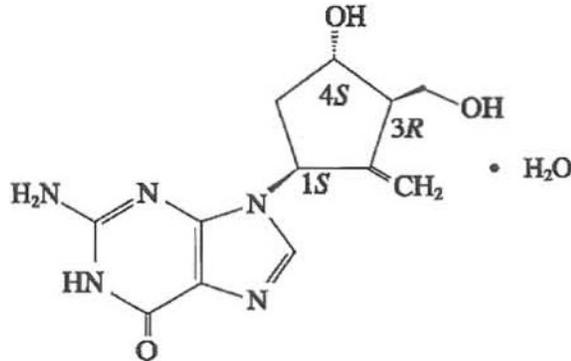
16. BMS is the holder of New Drug Application (“NDA”) No. 21-797, which relates to tablets containing 0.5 mg and 1 mg of entecavir. On March 29, 2005, the United States Food and Drug Administration (“FDA”) approved the marketing of the tablets described in NDA No. 21-797 for the treatment of chronic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

17. 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®.

18. BMS is the assignee of all rights in the ’244 Patent.

19. 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:



20. 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-(1 $\alpha$ ,3 $\alpha$ ,4 $\beta$ )]-2-Amino-1,9-dihydro-9-[4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6H-purin-6-one.”

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

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

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

### **COUNT I**

#### **Infringement of U.S. Patent No. 5,206,244 (ANDA No. 203905)**

24. BMS repeats and realleges paragraphs 1-23 above as if set forth herein.

25. Sandoz submitted or caused to be submitted ANDA No. 203905 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 ("Sandoz's Entecavir Tablets").

26. On information and belief, ANDA No. 203905 seeks approval to market Sandoz'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.

27. By letter dated May 11, 2012 (the "Notice Letter") and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Sandoz notified BMS that it had submitted ANDA No. 203905 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Sandoz's Entecavir Tablets prior to the expiration of the '244 Patent.

28. BMS did not receive the Notice Letter until May 14, 2012.

29. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz notified BMS by means of the Notice Letter that Sandoz believed the '244 Patent to be invalid, unenforceable, and/or not

infringed by the manufacture, use, importation, sale, or offer for sale of Sandoz's Entecavir Tablets.

30. Statutory section 355(j) requires, *inter alia*, certification by the ANDA applicant that, in its opinion and to the best of its knowledge, the subject patent (*i.e.*, the '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 . . . ." The statute also requires that a so-called Paragraph IV notice letter "include 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." Further, FDA Regulation 21 C.F.R. § 3111.95(c)(6)(ii) 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."

31. Sandoz alleged in its Notice Letter that claims 1-6 and 8-11 of the '244 Patent are invalid as obvious and that claims 7, 9, and 11 are not infringed by Sandoz's Entecavir Tablets literally or under the doctrine of equivalents.

32. Sandoz did not assert in its Notice Letter that claims 1-6, 8, or 10 of the '244 Patent are not infringed by Sandoz's Entecavir Tablets.

33. By filing ANDA No. 203905 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Sandoz's Entecavir Tablets before the '244 Patent's expiration, Sandoz has committed an act of infringement of the '244 Patent under 35 U.S.C. § 271(e)(2). Sandoz did not deny in its Notice Letter that the filing of ANDA No. 203905 constitutes an act of infringement of claims 1-6, 8, and 10 of the '244 Patent to the extent that the claims are not found invalid or unenforceable.

34. On information and belief, the commercial manufacture, use, offer for sale, and sale in the United States of Sandoz's Entecavir Tablets and importation of Sandoz's Entecavir Tablets into the United States will infringe, induce infringement and/or contributorily infringe one or more claims of the '244 Patent. Sandoz did not deny in its Notice Letter that the commercial manufacture, use, offer for sale, or sale in the United States of Sandoz's Entecavir Tablets and importation of Sandoz's Entecavir Tablets into the United States would constitute an act of infringement of claims 1-6, 8, and 10 of the '244 Patent to the extent that claims are not found invalid or unenforceable.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff BMS respectfully requests the following relief:

- (a) A judgment declaring that the effective date of any approval of Sandoz's ANDA No. 203905 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 Sandoz;
- (c) A permanent injunction against any infringement of the '244 Patent by Sandoz, 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: June 21, 2012

/s/ Jeffrey B. Bove

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