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

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| BRISTOL-MYERS SQUIBB COMPANY,<br><br>Plaintiff,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>Defendants. | Civil Action No. 10-805 HB<br><br>**JURY TRIAL DEMANDED** |

**DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S**
**ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), by and through the undersigned attorneys, answers the Complaint of Plaintiff Bristol-Myers Squibb Company ("Plaintiff") as follows:

## NATURE OF THE ACTION

1. Defendant admits that Plaintiff's complaint is for patent infringement under the patent laws of the United States.

## THE PARTIES

2. On information and belief, Defendant admits the allegations of paragraph 2.

3. Defendant admits the allegations of paragraph 3.

4. Defendant admits the allegations of paragraph 4.

5. Paragraph 5 contains conclusions of law for which no response is required. To the extent a response is required, Defendant denies that Teva Ltd. is properly a defendant. Defendant Teva USA admits that it is an indirect wholly-owned subsidiary of Teva Ltd. and that

Teva USA and Teva Ltd. share officers and directors in common. Defendant denies the remaining allegations of paragraph 5.

6. Paragraph 6 contains conclusions of law for which no response is required. To the extent a response is required, Defendant states that the allegations are vague and ambiguous and on that basis deny the same.

**JURISDICTION AND VENUE**

7. Paragraph 7 contains conclusions of law for which no response is required. To the extent a response is required, Defendant admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Defendant denies the remaining allegations of paragraph 7.

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, Defendant admits that Teva USA is a Delaware corporation. Defendant further admits that this Court has personal jurisdiction over Teva USA for the purpose of this action. Defendant further admits that Teva USA is registered to do business with the Delaware Department of State, Division of Corporations and that Corporate Creations Network, Inc., 3411 Silverside Road, Rodney Building #104, Wilmington, DE 19810 is authorized to accept service on behalf of Teva USA.

9. Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Defendant admits that this Court has personal jurisdiction over Teva USA for the purpose of this action. As to any remaining allegations, Defendant states that the allegations are vague and ambiguous and on that basis denies the same.

10. Defendant denies that this Court has personal jurisdiction over Teva Ltd. for the purpose of this action and denies that Teva Ltd. is properly a defendant. Defendant denies the remaining allegations of paragraph 10.

11. Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, Defendant Teva USA admits that it was a party to *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. Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Defendant admits the allegations of paragraph 12.

**BACKGROUND**

13. On information and belief, Defendant admits that the FDA's Orange Book indicates that BMS is the holder of NDA No. 21-797, which relates to tablets containing 0.5 mg and 1 mg of entecavir. Defendant further admits that the Orange Book indicates that the FDA approved NDA No. 21-797 on March 29, 2005. Defendant further states that the approved indication for marketing entecavir is set forth in the FDA-approved label for Baraclude®. Defendant admits that the product described in NDA No. 21-797 is sold under the trademark Baraclude®. Defendant denies any remaining allegations of paragraph 13.

14. Defendant admits that on April 27, 1993, the United States Patent and Trademark Office issued U.S. Patent No. 5,206,244 ("the '244 patent") and that it is entitled "Hydroxymethyl (Methylenecyclopentyl) Purines and Pyrimidines." Defendant specifically denies that the '244 patent was "duly and legally issued." Defendant admits that the '244 patent

is listed in the FDA Orange Book entry for Baraclude® and admits that the patent claims, among other things, entecavir. Defendant denies the remaining allegations of paragraph 14.

15. Defendant admits that E.R. Squibb & Sons, Inc. is listed as the assignee on the face of the '244 patent. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15, and therefore denies the same.

16. On information and belief, Defendant admits the allegations of paragraph 16.

17. Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, Defendant admits that 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." Defendant admits that the name for entecavir in the '244 patent is "[1S-(1α,3α,4β)]-2-amino-1,9-dihydro-9-[4-hydroxy-3-(hydroxymethyl)-2-methylene-cyclopentyl]-6H-purin-6-one." Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17, and therefore denies the same.

18. Defendant admits that the face of the '244 patent identifies Robert Zahler and William A. Slusarchyk as "inventors."

19. Defendant admits that according to the USPTO assignment records, Robert Zahler and William A. Slusarchyk assigned the '244 patent to E.R. Squibb & Sons, Inc. on September 13, 1991.

20. Defendant admits that according to the USPTO assignment records, the '244 patent was assigned to BMS on September 8, 2004.

**COUNT I**
**ALLEGED INFRINGEMENT OF U.S. PATENT NO. 5,206,244 (ANDA No. 202122)**

21. Defendant repeats and incorporates by reference its answers to paragraphs 1-20.

22. Defendant admits the allegations of paragraph 22 with respect to Teva USA. Defendant denies the allegations with respect to Teva Ltd.

23. Defendant admits the allegations of paragraph 23 with respect to Teva USA. Defendant denies the allegations with respect to Teva Ltd.

24. Defendant admits that by letter dated August 11, 2010, Teva USA notified Plaintiff, as required by 21 U.S.C. § 505(j)(2)(B)(ii), that it had submitted a Paragraph IV certification, in conjunction with ANDA No. 202122, that the '244 patent was invalid, unenforceable, and/or not infringed. Defendant further admits that Teva USA is seeking FDA approval to engage in the commercial manufacture, use and/or sale of Teva USA's product that is the subject of ANDA No. 20122 prior to the expiration of the '244 patent. Defendant denies any remaining allegations of paragraph 24.

25. Defendant is without information sufficient to form a belief as to the truth of the allegation in paragraph 25 and therefore denies the same.

26. Defendant admits that by letter dated August 11, 2010, Teva USA notified Plaintiff that it had submitted a Paragraph IV certification, in conjunction with ANDA No. 202122, that the '244 patent was invalid, unenforceable, and/or not infringed. The remaining allegations of paragraph 26 contain conclusions of law for which no response is required.

27. Defendant admits the allegations of paragraph 27 with respect to Teva USA. Defendant denies any remaining allegations of paragraph 27.

28. Defendant denies that Teva USA did not assert in its Notice Letter that claims 1-6 or 8 of the '244 Patent are not infringed. The remaining allegations of paragraph 28 contain conclusions of law for which no response is required. To the extent that a response is required, Defendant denies all other allegations of paragraph 28.

29. Defendant admits that Teva USA submitted ANDA No. 202122 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Entecavir Tablets before the expiration of the '244 patent. Defendant further admits that filing an ANDA containing a paragraph IV certification to an Orange Book listed patent vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Defendant denies the remaining allegations of paragraph 29.

30. Defendant denies the allegations of paragraph 30.

**PRAYER FOR RELIEF**

Defendant denies that Plaintiff is entitled to any relief from the Court.

**AFFIRMATIVE DEFENSES**

**First Affirmative Defense**

Teva USA's product that is the subject of ANDA No. 202122 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '244 patent.

**Second Affirmative Defense**

One or more claims of the '244 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

**Third Affirmative Defense**

Plaintiff's complaint fails to state a claim upon which relief may be granted.

**Fourth Affirmative Defense**

Teva Pharmaceutical Industries, Ltd. is not a proper party to this action.

**Fifth Affirmative Defense**

This Court lacks personal jurisdiction over Teva Pharmaceutical Industries, Ltd.

**Sixth Affirmative Defense**

Any additional defenses or counterclaims that discovery may reveal.

**DEFENDANT'S REQUEST FOR RELIEF**

WHEREFORE, Defendant respectfully requests that the Court enter a Judgment and Order in its favor and against Plaintiff as follows:

A. dismissing Teva Ltd. as a party;

B. declaring that Teva USA's product that is the subject of ANDA No. 202122 does not and will not infringe any valid and enforceable claim of the '244 patent;

C. declaring that one or more claims of the '244 patent are invalid;

D. declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendant its attorneys' fees, costs, and expenses in this action;

E. preliminarily and permanently enjoining Plaintiff, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff, from utilizing the patent-in-suit to block, hamper, hinder or obstruct FDA approval of Teva USA's proposed product;

F. permanently enjoining Plaintiff, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff, from asserting or otherwise seeking to enforce the patent-in-suit against Defendant or anyone in privity with Defendant;

G. awarding Defendant its costs;

H. awarding Defendant any further and additional relief as the Court deems just and proper; and

I. dismissing all claims asserted by Plaintiff.

**JURY DEMAND**

Defendant Teva Pharmaceuticals USA, Inc. requests a jury trial on all issues so triable.

**PHILLIPS, GOLDMAN & SPENCE, P.A.**

Dated: October 26, 2010

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