IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC. Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC. Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiff Millennium Pharmaceuticals, Inc. ("Millennium") brings this action for patent infringement against Teva Parenteral Medicines, Inc. ("Teva Parenteral") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Defendants"). Millennium alleges as follows:

THE PARTIES

1. Millennium is a Delaware corporation, having its principal place of business at 40 Landsdowne Street, Cambridge, MA 02139. Millennium is engaged in the business of developing, manufacturing, and selling pharmaceutical drug products, particularly for use in the therapeutic area of oncology.

2. Upon information and belief, Defendant Teva Parenteral is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, Teva Parenteral is a wholly owned and directly controlled subsidiary of Teva USA. Upon information and belief, Teva Parenteral develops and markets generic injectable drug products, which constitute Teva USA's line of injectable products.

3. Upon information and belief, Teva USA is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA markets a wide range of generic drug products, and specifically markets injectable drug products through and with Teva Parenteral.

4. Upon information and belief, Teva USA uses and works with Teva Parenteral to carry out its business of importing, manufacturing, formulating, filling, labeling, and packaging finished dosage forms of injectable generic drug products for distribution in Delaware and throughout the United States.

5. Upon information and belief, Teva USA has endeavored to completely integrate Teva Parenteral's business into the operations of Teva USA.

NATURE OF THE ACTION

6. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 91-035 filed by Teva Parenteral with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Millennium's highly successful VELCADE® (bortezomib) for Injection pharmaceutical product sold in the United States.

JURISDICTION

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. The Court has personal jurisdiction over the Defendants, each of which is a Delaware corporation.

COUNT I FOR PATENT INFRINGEMENT

9. United States Patent No. 6,713,446 ("the '446 patent"), entitled "Formulation of Boronic Acid Compounds," was duly and legally issued to The United States of America as Represented by the Secretary of Health and Human Services by the United States Patent and Trademark Office on March 30, 2004. The '446 patent expires on January 25, 2022. A true and correct copy of the '446 patent is attached as Exhibit A.

10. United States Patent No. 6,958,319 ("the '319 patent"), entitled "Formulation of Boronic Acid Compounds," was duly and legally issued to The United States of America as Represented by the Secretary of Health and Human Services by the United States Patent and Trademark Office on October 25, 2005. The '319 patent expires on January 25, 2022. A true and correct copy of the '319 patent is attached as Exhibit B.

11. Millennium has had an exclusive license to the '446 patent and the '319 patent since December 2, 2002, by virtue of an exclusive worldwide License Agreement for the research, development, and manufacture of MLN341 (bortezomib) for distribution, sale and use in oncology disease states. Pursuant to the license, Millennium has the right to bring suit in its own name, at its own expense, and on its own behalf for infringement of the '446 and '319 patents.

12. Millennium is the holder of approved New Drug Application No. 21-602 for the use of VELCADE® as a treatment for multiple myeloma patients and mantle cell lymphoma patients who have received at least one prior therapy.

13. Upon information and belief, Teva Parenteral filed or caused to be filed with the FDA, in Rockville, Maryland, ANDA No. 91-035 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, or sale of Bortezomib for Injection, 3.5 mg/vial, before the

expiration dates of the '446 or '319 patents. Upon information and belief, ANDA No. 91-035 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the '446 patent and the '319 patent are invalid, unenforceable, or would not be infringed by the manufacture, use, or sale of Defendants' Bortezomib for Injection pharmaceutical product.

14. Upon information and belief, Teva USA participated in the submission of ANDA No. 91-035 or otherwise acted in concert with Teva Parenteral in the submission of ANDA No. 91-035.

15. Upon information and belief, Teva USA exercises control over Teva Parenteral and conducts its U.S. injectable generic drug product operations through and with Teva Parenteral.

16. Upon information and belief, if ANDA No. 91-035 is approved, it is the intention of Teva USA and Teva Parenteral that their Bortezomib for Injection pharmaceutical product will be distributed in the United States by or through Teva USA and/or Teva Parenteral.

17. Defendants caused to be sent to Millennium and the United States government a letter ("Notice Letter") dated January 16, 2009, notifying Millennium and the United States government that Teva Parenteral had filed ANDA No. 91-035 for Bortezomib for Injection (3.5 mg/vial) and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges noninfringement of certain claims of the '446 and '319 patents and that the remaining claims are invalid.

18. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA 91-035 to the FDA seeking approval for the commercial manufacture, use, or sale of Bortezomib for Injection before the expiration of the '446 patent and the '319 patent constitutes an act of infringement. If

ANDA No. 91-035 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale, or importation of their Bortezomib for Injection pharmaceutical product would infringe one or more claims of the '446 patent and the '319 patent under 35 U.S.C. § 271(a)-(c).

19. Upon information and belief, Defendants had actual knowledge of the '446 and '319 patents prior to filing ANDA No. 91-035 and did not exercise due care in analyzing the '446 patent and the '319 patent and presenting arguments in their paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and in their Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

20. Millennium will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Millennium has no adequate remedy at law.

21. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Millennium and Defendants concerning liability for the infringement of the '446 patent and the '319 patent. Defendants' actions create a reasonable apprehension of irreparable harm and loss resulting from their threatened imminent actions.

COUNT II FOR DECLARATORY JUDGMENT

22. Millennium realleges and incorporates by reference paragraphs 1-21.

23. Upon information and belief, if ANDA No. 91-035 is approved, it is the intention of Teva USA and Teva Parenteral that their Bortezomib for Injection pharmaceutical product will be distributed in the United States by or through Teva USA and/or Teva Parenteral.

24. Upon information and belief, Defendants know that physicians will use their generic Bortezomib for Injection pharmaceutical product in accordance with the labeling sought

by ANDA No. 91-035 and Defendants will therefore infringe one or more claims of the '446 patent and the '319 patent.

25. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell their Bortezomib for Injection pharmaceutical product soon after the FDA approves ANDA No. 91-035.

26. Such conduct will constitute infringement of one or more claims of the '446 patent and the '319 patent under 35 U.S.C. § 271.

27. Defendants' infringing commercial manufacture, use, offer to sell, sale, or importation of their Bortezomib for Injection pharmaceutical product complained of herein will begin following FDA approval of ANDA No. 91-035.

28. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Millennium and Defendants concerning liability for the infringement of the '446 patent and the '319 patent. Defendants' actions create a reasonable apprehension of irreparable harm and loss resulting from their threatened imminent actions.

PRAYER FOR RELIEF

Wherefore, Plaintiff Millennium demands judgment against Defendants Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. and respectfully requests that this Court grant the following relief:

(a) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 91-035 to obtain approval for the commercial manufacture, use, or sale of their Bortezomib for Injection pharmaceutical product in the United States prior to the expiration of the '446 was an act of infringement of one or more claims of the '446 patent;

(b) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 91-035 to obtain approval for the commercial manufacture, use, or sale of their Bortezomib for Injection pharmaceutical product in the United States prior to the expiration of the '319 patent was an act of infringement of one or more claims of the '319 patent;

(c) A declaration that, if Defendants' ANDA No. 91-035 is approved, Defendants' commercial manufacture, use, offer for sale, sale, or importation of their Bortezomib for Injection pharmaceutical product in the United States would constitute infringement of one or more claims of the '446 patent;

(d) A declaration that, if Defendants' ANDA No. 91-035 is approved, Defendants' commercial manufacture, use, offer for sale, sale, or importation of their Bortezomib for Injection pharmaceutical product in the United States would constitute infringement of one or more claims of the '319 patent;

(e) An Order, in accordance with 35 U.S.C. § 271(e)(4)(A), providing that the effective date of any approval of ANDA No. 91-035 relating to Bortezomib for Injection shall be no earlier than the expiration date of the '446 and '319 patents;

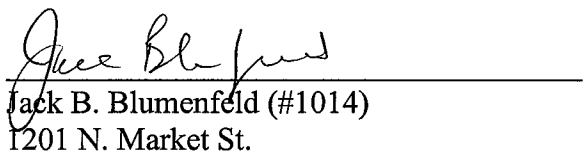
(f) An Order permanently enjoining Defendants from the commercial manufacture, use, offer for sale, sale, or importation of their Bortezomib for Injection pharmaceutical product until after expiration of the '446 and '319 patents, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

(g) A declaration that this is an exceptional case and an award of attorney's fees to Millennium under 35 U.S.C. §§ 285 and 271(e)(4);

(h) Millennium's reasonable costs of suit incurred; and

(i) Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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