IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, LLC, FRESENIUS KABI USA, INC., and FRESENIUS KABI PHARMACEUTICALS HOLDING, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiff Millennium Pharmaceuticals, Inc., by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Fresenius Kabi USA of New Drug Application ("NDA") No. 205004 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a bortezomib product prior to the expiration of U.S. Patent Nos. 6,713,446 and 6,958,319.

PARTIES

2. Plaintiff Millennium Pharmaceuticals, Inc. ("Millennium") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts. Millennium is engaged in the business of developing, manufacturing, and selling pharmaceutical drug products, particularly for use in the therapeutic area of oncology.

3. Upon information and belief, Defendant Fresenius Kabi Pharmaceuticals Holding, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at Else-Kroener-Strasse 1, 61352 Bad Homburg v.d.H., Germany. Upon information and belief, the business of Fresenius Kabi Pharmaceuticals Holding, Inc. consists exclusively of that of Defendant Fresenius Kabi USA, Inc., its wholly-owned, operating subsidiary, which develops, manufactures, distributes, markets, and sells its generic drug products throughout the United States.

4. Upon information and belief, Defendant Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1501 Woodfield Road, Suite 300 East, Schaumburg, Illinois, 60173. Upon information and belief, Fresenius Kabi USA, Inc. is a wholly-owned subsidiary of Fresenius Kabi Pharmaceuticals Holding, Inc. and is controlled and/or dominated by Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, Fresenius Kabi USA, Inc. itself and through its wholly-owned subsidiary and agent Defendant Fresenius Kabi USA, LLC, develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Fresenius Kabi Pharmaceuticals Holding, Inc.

5. Upon information and belief, Defendant Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 1501 Woodfield Road, Suite 300 East, Schaumburg, Illinois, 60173. Upon information and belief, Fresenius Kabi USA, LLC is a wholly-owned subsidiary of Fresenius Kabi USA, Inc. Upon information and belief, Fresenius Kabi USA, LLC is controlled and/or dominated by Fresenius Kabi USA, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc.

Upon information and belief, Fresenius Kabi USA, LLC develops, manufactures, and/or distributes generic drug products for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Fresenius Kabi USA, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc. Fresenius Kabi Pharmaceuticals Holding, Inc., Fresenius Kabi USA, Inc., and Fresenius Kabi USA, LLC are collectively referred to hereinafter as "Fresenius" or "Defendants."

6. Upon information and belief, following any FDA approval of NDA No. 205004, Fresenius will make, use, import, offer to sell, and/or sell the bortezomib products that are the subject of NDA No. 205004 throughout the United States, including in the State of Delaware, and/or import such products into the United States.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

9. The Court has personal jurisdiction over Defendants because, among other things, all three Defendants have submitted themselves to the jurisdiction of courts in Delaware by virtue of their incorporation or organization under Delaware law.

10. The Defendants are also subject to personal jurisdiction in Delaware because, among other things, they each directly and/or through wholly-owned subsidiaries, manufacture, market, distribute and/or sell generic drugs throughout the United States and within the State of Delaware and therefore purposefully avail themselves of the privilege of conducting activities within the State of Delaware. On information and belief, Fresenius Kabi USA, LLC is

registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

BACKGROUND

11. United States Patent No. 6,713,446 ("the '446 patent"), entitled "Formulation of Boronic Acid Compounds" (Exhibit A hereto), was duly and legally issued on March 30, 2004. The '446 patent, which is owned by the United States of America as Represented by the Secretary of Health and Human Services, will expire on January 25, 2022.

12. United States Patent No. 6,958,319 ("the '319 patent"), entitled "Formulation of Boronic Acid Compounds" (Exhibit B hereto), was duly and legally issued on October 25, 2005. The '319 patent, which is owned by the United States of America as Represented by the Secretary of Health and Human Services, will expire on January 25, 2022.

13. Millennium has had an exclusive license to the '446 and '319 patents 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 this 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.

14. VELCADE® (bortezomib) is a proteasome inhibitor, for intravenous or subcutaneous administration, approved by the FDA for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma who have received at least one prior therapy.

15. Millennium sells VELCADE® in the United States pursuant to New Drug Application No. 21-602 which was approved by the FDA in 2003 and pursuant to several

subsequent supplemental new drug applications for additional indications and a new route of administration which have also been approved by the FDA.

16. VELCADE®, or its use, is covered by one or more claims of the '446 and '319 patents, which have been listed in connection with VELCADE® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

17. By letter dated February 5, 2012, and received February 6, 2012 (the "Notice Letter"), Fresenius notified Millennium that it had submitted an NDA for bortezomib injectable, 3.5 mg/vial, ("the Fresenius 505(b)(2) Product") to the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. The FDA assigned NDA No. 205004 to the application.

18. In the Notice Letter, Fresenius stated that its 505(b)(2) NDA included certifications pursuant to 21 U.S.C. § 355(b)(3)(B) with respect to the '446 and '319 patents and alleged that the '446 and '319 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Fresenius 505(b)(2) Product.

19. This action is being commenced before the expiration of forty-five days from the date of Plaintiff's receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,713,446

20. Plaintiff incorporates each of the preceding paragraphs 1 – 19 as if fully set forth herein.

21. Fresenius' submission of NDA No. 205004 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the

Fresenius 505(b)(2) Product before the expiration of the '446 patent is an act of infringement of the '446 patent.

22. The commercial manufacture, use, offer for sale, sale and/or importation of the Fresenius 505(b)(2) Product would infringe one or more claims of the '446 patent under the doctrine of equivalents.

23. Fresenius had knowledge of the '446 patent when it submitted its 505(b)(2) NDA to the FDA.

24. Upon information and belief, use of the Fresenius 505(b)(2) Product in accordance with and as directed by Fresenius' proposed labeling for that product would infringe one or more claims of the '446 patent under the doctrine of equivalents.

25. Upon information and belief, Fresenius intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Fresenius 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 205004.

26. Upon information and belief, Fresenius will actively induce infringement of the '446 patent should its NDA No. 205004 be approved, and plans and intends to, and will do so immediately and imminently upon approval.

27. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '446 patent and/or actively inducing infringement of the '446 patent.

28. Unless Fresenius is enjoined from infringing the '446 patent and/or actively inducing infringement of the '446 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 6,958,319

29. Plaintiff incorporates each of the preceding paragraphs 1 – 28 as if fully set forth herein.

30. Fresenius' submission of NDA No. 205004 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Fresenius 505(b)(2) Product before the expiration of the '319 patent is an act of infringement of the '319 patent.

31. The commercial manufacture, use, offer for sale, sale and/or importation of the Fresenius 505(b)(2) Product would infringe one or more claims of the '319 patent under the doctrine of equivalents.

32. Fresenius had knowledge of the '319 patent when it submitted its 505(b)(2) NDA to the FDA.

33. Upon information and belief, use of the Fresenius 505(b)(2) Product in accordance with and as directed by Fresenius' proposed labeling for that product would infringe one or more claims of the '319 patent under the doctrine of equivalents.

34. Upon information and belief, Fresenius intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Fresenius 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 205004.

35. Upon information and belief, Fresenius will actively induce infringement of the '319 patent should its NDA No. 205004 be approved, and plans and intends to, and will do so immediately and imminently upon approval.

36. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '319 patent and/or actively inducing infringement of the '319 patent.

37. Unless Fresenius is enjoined from infringing the '319 patent and/or actively inducing infringement of the '319 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court grant the following relief:

(a) A judgment that Fresenius' submission of NDA No. 205004 was an act of infringement of the '446 and '319 patents, and that Defendants' manufacture, use, offer to sell, sale, or importation of the Fresenius 505(b)(2) Product prior to the expiration of the '446 and '319 patents, will infringe and/or actively induce infringement of the '446 and '319 patents;

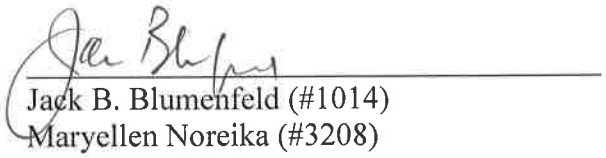
(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius' NDA No. 205004, or any product or compound that infringes the '446 and '319 patents, shall not be earlier than the expiration of the '446 and '319 patents;

(c) An Order permanently enjoining Fresenius, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, have made, using, offering to sell, selling, marketing, distributing, or importing the Fresenius 505(b)(2) Product, or any product or compound that infringes the '446 and '319 patents, or inducing the infringement of the '446 and '319 patents until after the expiration of the '446 and '319 patents;

(d) A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiff pursuant to 35 U.S.C. §§ 285 and 271(e)(4), together with its reasonable costs; and

(e) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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