IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.	)	
Plaintiff,	)	
v.	)	C.A. No. _____
APOTEX CORP. and APOTEX 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 Apotex Inc. of Abbreviated New Drug Application ("ANDA") No. 205533 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of VELCADE® 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 Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada. Upon information and belief, Apotex Inc. develops, and manufactures generic pharmaceutical products throughout the United States, including in this judicial district.

5. Upon information and belief, Apotex Inc. is in the business of manufacturing drug products for the purpose of sale within the United States, including in the state of Delaware.

6. Upon information and belief, Apotex Corp. serves as Apotex Inc.'s United States sales agent and distributor and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in Delaware.

7. Upon information and belief, Apotex Corp. and Apotex Inc. (collectively, "Apotex") are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arm's length.

8. Upon information and belief, following FDA approval of ANDA No. 205533, Apotex will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 205533 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

9. 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.

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

11. The Court has personal jurisdiction over Apotex Corp. because, among other things, upon information and belief, Apotex Corp. is a Delaware corporation with a registered agent in Delaware; Apotex Corp. is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy – Wholesale" pursuant to 24 Del. C. § 2540; and it is in the business of marketing and selling drug products throughout the United States, including in Delaware.

12. The Court has personal jurisdiction over Apotex Inc. because, among other things, Apotex Inc. markets and sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. In addition, upon information and belief, Apotex Inc. has previously availed itself of this forum for the purpose of litigating its patent infringement disputes. For example, on September 9, 2013, Apotex Inc. filed a counterclaim seeking a declaratory judgment of non-infringement and invalidity in *UCB, Inc. v. Apotex Corp. and Apotex Inc.*, C.A. No. 13-1209 (D. Del.). Apotex Inc. has also availed itself of this forum for the purposes of litigating business disputes, and on February 16, 2012, filed suit in *Apotex Inc. v. Senju Pharmaceutical Co. et al.*, No. 12-196 (D. Del.).

BACKGROUND

13. 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.

14. 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.

15. 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.

16. 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.

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

18. 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.”

19. By letter dated October 2, 2013, and received October 3, 2013 (the “Notice Letter”), Apotex notified Millennium that it had submitted to the FDA ANDA No. 205533 for Bortezomib for Injection, 3.5 mg/vial, a generic version of VELCADE® (“the Apotex ANDA Product”).

20. In the Notice Letter, Apotex stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) 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 Apotex ANDA Product.

21. 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

22. Plaintiff incorporates each of the preceding paragraphs 1 – 21 as if fully set forth herein.

23. Apotex’s submission of ANDA No. 205533 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Apotex ANDA Product before the expiration of the ’446 patent is an act of infringement of the ’446 patent.

24. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex ANDA Product would infringe one or more claims of the ’446 patent.

25. Apotex had knowledge of the ’446 patent when it submitted its ANDA to the FDA.

26. Upon information and belief, use of the Apotex ANDA Product in accordance with and as directed by Apotex’s proposed labeling for that product would infringe one or more claims of the ’446 patent.

27. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205533.

28. Upon information and belief, Apotex will actively induce infringement of the ’446 patent when its ANDA is approved, and plans and intends to, and will do so immediately and imminently upon approval.

29. Upon information and belief, Apotex 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.

30. Unless Apotex 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

31. Plaintiff incorporates each of the preceding paragraphs 1 – 30 as if fully set forth herein.

32. Apotex’s submission of ANDA No. 205533 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Apotex ANDA Product before the expiration of the ’319 patent is an act of infringement of the ’319 patent.

33. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex ANDA Product would infringe one or more claims of the ’319 patent.

34. Apotex had knowledge of the ’319 patent when it submitted its ANDA to the FDA.

35. Upon information and belief, use of the Apotex ANDA Product in accordance with and as directed by Apotex’s proposed labeling for that product would infringe one or more claims of the ’319 patent.

36. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205533.

37. Upon information and belief, Apotex will actively induce infringement of the ’319 patent when its ANDA is approved, and plans and intends to, and will do so immediately and imminently upon approval.

38. Upon information and belief, Apotex 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.

39. Unless Apotex 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 Apotex’s submission of ANDA No. 205533 was an act of infringement of the ’446 and ’319 patents, and that Apotex’s manufacture, use, offer to sell, sale,

or importation of the Apotex ANDA 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 Apotex's ANDA No. 205533, 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 Apotex, 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 Apotex ANDA 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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