IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
WOCKHARDT BIO AG and WOCKHARDT USA LLC,	)	
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 Defendants Wockhardt Bio AG ("Wockhardt Bio") and Wockhardt USA LLC ("Wockhardt USA," and with Wockhardt Bio, "Wockhardt") of Abbreviated New Drug Application ("ANDA") No. 208497 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of VELCADE® for Injection prior to the expiration of U.S. Patent Nos. 6,713,446 and 6,958,319 (the "Patents-in-Suit").

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 02139. 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, Wockhardt Bio is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Grafenauweg 6 6300 ZUG, Switzerland.

4. Upon information and belief, Wockhardt Bio, itself and through its subsidiaries and agents, manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

5. Upon information and belief, Wockhardt Bio, itself and through its subsidiaries and agents, including Wockhardt USA, manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

6. Upon information and belief, Wockhardt USA is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 20 Waterview Blvd., Parsippany, NJ 07054.

7. Upon information and belief, Wockhardt USA is a wholly owned subsidiary of Morton Grove Pharmaceuticals Inc., which is a wholly owned subsidiary of Wockhardt Holding Corp., which is a wholly owned subsidiary of Wockhardt Bio.

8. Upon information and belief, Wockhardt USA is the U.S. agent for service on Wockhardt Bio.

9. Upon information and belief, following any FDA approval of ANDA No. 208497, Wockhardt, itself and through its subsidiaries and agents, will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 208497 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

JURISDICTION AND VENUE

10. 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.

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

12. This Court has jurisdiction over Wockhardt USA because, among other things, it is a limited liability company organized and existing under the laws of the State of Delaware. Wockhardt USA is registered to conduct business in the State of Delaware, Department of State: Division of Corporations, under file number 3769747 and maintains as a registered agent, Corporation Service Company, registered at 2711 Centerville Rd. Suite 400, Wilmington, DE 19808.

13. This Court also has personal jurisdiction over Wockhardt Bio because, among other things, it has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that it should reasonably anticipate being haled into court here. On information and belief, Wockhardt Bio has persistent, systematic and continuous contacts with Delaware as set forth below.

14. This Court has jurisdiction over Wockhardt Bio because, among other things, of its creation of one or more subsidiaries in Delaware (*e.g.*, Wockhardt USA).

15. This Court has jurisdiction over Wockhardt Bio because, among other things, of its appointment of an agent for service of process in the State of Delaware, *i.e.*, Wockhardt USA.

16. The court has personal jurisdiction over each of the Defendants because, among other things, they have each committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and

injury to Millennium, a Delaware corporation, which manufactures VELCADE® for Injection for sale and use throughout the United States, including the State of Delaware.

17. Upon information and belief, Wockhardt Bio, itself and through its subsidiaries and agents, including Wockhardt USA, currently manufactures and distributes for sale numerous drug products throughout the United States, including in this judicial district.

18. Upon information and belief, Wockhardt Bio directs the operations, management and activities of Wockhardt USA in the United States.

19. Upon information and belief, Wockhardt Bio, directly or through Wockhardt USA, routinely files ANDAs seeking FDA approval to market its drug products in the United States.

20. Upon information and belief, Wockhardt regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Upon information and belief, Wockhardt Bio and Wockhardt USA have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

21. Upon information and belief, Wockhardt Bio and Wockhardt USA operate as an integrated, unitary generic pharmaceutical business.

22. Upon information and belief, Wockhardt Bio and Wockhardt USA derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

23. In the alternative as to Wockhardt Bio, the Court may exercise personal jurisdiction over Wockhardt Bio pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a)

Millennium's claims arise under federal law; (b) Wockhardt Bio is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Wockhardt Bio has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Wockhardt Bio satisfies due process.

24. Upon information and belief, Wockhardt Bio and Wockhardt USA will manufacture, market, and/or sell within the United States the generic version of VELCADE® for Injection described in ANDA No. 208497 if FDA approval is granted. If ANDA No. 208497 is approved, the Wockhardt generic version of VELCADE® for Injection charged with infringing the Patents-in-Suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

BACKGROUND

25. 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.

26. 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.

27. 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.

28. VELCADE® for Injection 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.

29. Millennium sells VELCADE® for Injection 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.

30. VELCADE® for Injection, and its preparation and use, are covered by one or more claims of the ’446 and ’319 patents, which have been listed in connection with VELCADE® for Injection in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”

31. For example, VELCADE® for Injection is the lyophilized form of the mannitol ester of bortezomib, which has the chemical name D-mannitol N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate, and which is covered by at least claim 20 of the ’446 patent. *See e.g.*, ’446 patent, claim 20 (“The lyophilized compound D-mannitol N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate.”); *see also* ’446 patent, claims 19, 46 and 49. Further, the preparation and/or use of VELCADE® for Injection are covered by at least claims 31, 32, 53, 57, and 61 of the ’446 patent.

32. In addition, VELCADE® for Injection is covered by at least claim 26 of the ’319 patent. *See, e.g.*, ’319 patent, claim 26 (“The lyophilized compound of claim 20, wherein said

compound is a sugar ester of N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronic acid."); *see also* '319 patent, claims 25, 54 and 57. Further, the preparation, and/or use of VELCADE® for Injection are covered by at least claims 40, 62, 66, and 70 of the '319 patent.

33. By letter dated December 9, 2015 (the "Notice Letter"), Wockhardt notified Millennium that it had submitted to the FDA ANDA No. 208497 for bortezomib for injection, 3.5 mg/vial, a generic version of VELCADE® for Injection ("the Wockhardt ANDA Product").

34. By filing ANDA No. 208497, Wockhardt has necessarily represented to the FDA that the Wockhardt ANDA Product has the same active ingredient, dosage form, and strength as VELCADE® for Injection and is bioequivalent to VELCADE® for Injection.

35. In the Notice Letter, Wockhardt 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, or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Wockhardt ANDA Product.

36. In the Notice Letter, however, Wockhardt does not contest infringement of claims 10, 20, 46, and 49 of the '446 patent. These claims are directed to the mannitol ester of bortezomib, the lyophilized mannitol ester of bortezomib, a compound comprising the lyophilized mannitol ester of bortezomib and a pharmaceutically acceptable carrier, and a lyophilized cake comprising the lyophilized mannitol ester of bortezomib, respectively.

37. Wockhardt has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 208497 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of the Wockhardt ANDA Product before the expiration of the terms of the '446 and '319 Patents.

38. The sale, offer for sale, importation, preparation, and/or use of the proposed Wockhardt ANDA Product for which Wockhardt seeks approval in its ANDA will directly and/or indirectly infringe one or more claims of the ’446 and ’319 Patents.

39. Millennium is entitled under 35 U.S.C. § 271(e)(4) to full relief from Wockhardt’s acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 208497 relating to the proposed Wockhardt ANDA Product shall not be earlier than the expiration of the ’446 and ’319 Patents.

40. This action was commenced before the expiration of forty-five days from the date of Millennium’s receipt of the Notice Letter.

41. On August 20, 2015, the Court entered an order in *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.*, C.A. No. 12-1011-GMS (consolidated), in which the Court held certain claims of the ’446 patent invalid due to obviousness.

42. On September 21, 2015, Millennium filed a notice of appeal from the Court’s August 20, 2015 order and August 24, 2015 judgment of invalidity.

COUNT I
Infringement of U.S. Patent No. 6,713,446

43. Millennium incorporates each of the preceding paragraphs 1-42 as if fully set forth herein.

44. Wockhardt’s submission of ANDA No. 208497 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Wockhardt ANDA Product before the expiration of the ’446 patent is an act of infringement of the ’446 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Wockhardt intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Wockhardt ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208497.

46. The commercial manufacture, use, offer for sale, sale and/or importation of the Wockhardt ANDA Product would directly infringe one or more claims of the ’446 patent. For example, upon information and belief, the Wockhardt ANDA Product comprises the lyophilized mannitol ester of bortezomib and is covered by at least claims 19, 20, 46, and 49 of the ’446 patent. Further, upon information and belief, the manufacture of the Wockhardt ANDA Product is covered by at least claims 31, 32, 57, and 61 of the ’446 patent, and the preparation for administration of the Wockhardt ANDA Product is covered by at least claims 53 and 57 of the ’446 patent (collectively with claims 19, 20, 31, 32, 46, 49, and 61, the “’446 Asserted Claims”).

47. Wockhardt had knowledge of the ’446 patent when it submitted its ANDA to the FDA. Further, upon information and belief, Wockhardt knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Wockhardt ANDA Product will constitute infringement of at least the ’446 Asserted Claims. Upon information and belief, this knowledge is reflected through, among other things, the ’446 patent’s listing in the Orange Book in relation to VELCADE® for Injection, prior litigation related to the ’446 patent, and Wockhardt’s Notice Letter, which does not contest infringement of claims 10, 20, 46, and 49 of the ’446 patent.

48. Upon information and belief, use of the Wockhardt ANDA Product in accordance with and as directed by Wockhardt’s proposed labeling for that product would infringe one or more claims of the ’446 patent. For example, upon information and belief, Wockhardt’s proposed labeling will instruct that the Wockhardt ANDA Product is the lyophilized mannitol

ester of bortezomib and will instruct that the Wockhardt ANDA Product be prepared for administration in a manner covered by at least claims 46, 53, and 57 of the ’446 patent. Accordingly, Wockhardt will actively induce infringement under 35 U.S.C. § 271(b) of at least claims 46, 53, and 57 of the ’446 patent upon approval of ANDA No. 208497.

49. The Wockhardt ANDA Product is specially made to infringe at least the ’446 Asserted Claims, and has no substantial non-infringing use. Accordingly, the commercial manufacture, use, offer to sell, sale, or importation of the Wockhardt ANDA Product will contributorily infringe at least the ’446 Asserted Claims under 35 U.S.C. § 271(c).

50. Upon information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the ’446 patent.

51. Unless Wockhardt is enjoined from directly and indirectly infringing 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

52. Millennium incorporates each of the preceding paragraphs 1-51 as if fully set forth herein.

53. Wockhardt’s submission of ANDA No. 208497 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Wockhardt ANDA Product before the expiration of the ’319 patent is an act of infringement of the ’319 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Wockhardt intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Wockhardt ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208497.

55. The commercial manufacture, use, offer for sale, sale and/or importation of the Wockhardt ANDA Product would directly infringe one or more claims of the ’319 patent. For example, upon information and belief, the Wockhardt ANDA Product comprises the lyophilized mannitol ester of bortezomib and is covered by at least claims 25, 26, 54, and 57 of the ’319 patent. Further, upon information and belief, the manufacture of the Wockhardt ANDA Product is covered by at least claims 40, 66, and 70 of the ’319 patent, and the preparation for administration of the Wockhardt ANDA Product is covered by at least claims 62 and 66 of the ’319 patent (collectively with claims 25, 26, 40, 54, 57, and 70, the “’319 Asserted Claims”).

56. Wockhardt had knowledge of the ’319 patent when it submitted its ANDA to the FDA, including by virtue of the Orange Book listing of the ’319 patent in relation to VELCADE® for Injection. Further, upon information and belief, Wockhardt knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Wockhardt ANDA Product will constitute infringement of at least the ’319 Asserted Claims. Upon information and belief, this knowledge is reflected through, among other things, the ’319 patent’s listing in the Orange Book in relation to VELCADE® for Injection, prior litigation related to the ’319 patent, and Wockhardt’s Notice Letter.

57. Upon information and belief, use of the Wockhardt ANDA Product in accordance with and as directed by Wockhardt’s proposed labeling for that product would infringe one or more claims of the ’319 patent. For example, upon information and belief, Wockhardt’s proposed labeling will instruct that the Wockhardt ANDA Product is the lyophilized mannitol ester of bortezomib and will instruct that the Wockhardt ANDA Product be prepared for administration in a manner covered by at least claims 54, 62, and 66 of the ’319 patent.

Accordingly, Wockhardt will actively induce infringement under 35 U.S.C. § 271(b) of at least claims 54, 62, and 66 of the ’319 patent upon approval of ANDA No. 280497.

58. The Wockhardt ANDA Product is specially made to infringe at least the ’319 Asserted Claims, and has no substantial non-infringing use. Accordingly, the commercial manufacture, use, offer to sell, sale, or importation of the Wockhardt ANDA Product will contributorily infringe at least the ’319 Asserted Claims under 35 U.S.C. § 271(c).

59. Upon information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the ’319 patent.

60. Unless Wockhardt is enjoined from directly and indirectly infringing the ’319 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

PRAYER FOR RELIEF

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

(a) A judgment that Wockhardt’s submission of ANDA No. 208497 was an act of infringement of the ’446 and ’319 patents, and that Wockhardt’s manufacture, use, offer to sell, sale, or importation of the Wockhardt 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 Wockhardt’s ANDA No. 208497, 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 Wockhardt, 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 Wockhardt 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 Millennium 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

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff
Millennium Pharmaceuticals, Inc.

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Jason H. Liss
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Robert M. Galvin
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304
(650) 858-6000

January 22, 2016