

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS,
INC.

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

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C.A. No. _____

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 Amneal Pharmaceuticals LLC (“Amneal”) of Abbreviated New Drug Application (“ANDA”) No. 210049 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, Amneal is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

4. Upon information and belief, Amneal, 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, following any FDA approval of ANDA No. 210049, Amneal, 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. 210049 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

JURISDICTION AND VENUE

6. 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.

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

8. This Court has jurisdiction over Amneal because, among other things, it is a corporation organized and existing under the laws of the State of Delaware. Amneal is registered to conduct business in the State of Delaware, Department of State: Division of Corporations, under file number 3809030, and maintains as a registered agent, The Corporation Trust Company, registered at 1209 Orange St., Wilmington, DE 19801.

9. This Court also has personal jurisdiction over Amneal 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, Amneal has persistent, systematic and continuous contacts with Delaware as set forth below.

10. This Court has jurisdiction over Amneal because, among other things, of its appointment of an agent for service of process in the State of Delaware.

11. The court also has personal jurisdiction over Amneal because, among other things, it has 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. This Court also has personal jurisdiction over Amneal by virtue of, among other things, their systematic and continuous contacts with Delaware as set forth below.

12. Upon information and belief, Amneal, itself and through its subsidiaries and agents, currently manufactures and distributes for sale drug products throughout the United States, including in this judicial district.

13. Upon information and belief, Amneal routinely files ANDAs seeking FDA approval to market its drug products in the United States.

14. Upon information and belief, Amneal derives substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

15. Upon information and belief, Amneal will manufacture, market, and/or sell within the United States the generic version of VELCADE® for Injection described in ANDA No. 210049 if FDA approval is granted. If ANDA No. 210049 is approved, the generic version of VELCADE® for Injection charged with infringing the Patent-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.

16. Amneal has taken advantage of the jurisdiction of this Court by filing claims and counterclaims before this Court and/or consenting to personal jurisdiction, including in, e.g., *Amneal Pharmaceuticals LLC v. Teva Pharmaceuticals USA, Inc.*, 1:17-cv-00074 (D. Del.).

BACKGROUND

17. 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.

18. 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.

19. Millennium has had an exclusive license to the Patents-in-Suit 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 Patents-in-Suit.

20. 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.

21. 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.

22. VELCADE® for Injection, and its preparation and use, are covered by one or more claims of the Patents-in-Suit, 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."

23. For example, VELCADE® for Injection is the lyophilized 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 1-6, 8-16, 18-19, 21-27, 29-38, 47, 49, 58-59, 61-64, 66-67, and 69. Further, the preparation and/or use of VELCADE® for Injection are covered by at least claims 39-40, 42-44, 46, 50-51, 53-55, 57, 65, and 68 of the '446 patent.

24. 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 1-3, 5-9, 11-17, 19-22, 24-25, 27-28, 46, 55, 57, 71, 73, and 75. Further, the preparation, and/or use of VELCADE® for Injection are covered by at least claims 29-31, 33-36, 38-45, 47-48, 50-52, 54, 59-60, 62-64, 66-68, 70, 72, 74, and 76-78 of the '319 patent.

25. By letter dated February 28, 2017 (the “Notice Letter”), Amneal notified Millennium that it had submitted to the FDA ANDA No. 210049 for bortezomib for injection, 3.5 mg/vial, a generic version of VELCADE® for Injection (“the Amneal ANDA Product”).

26. In the Notice Letter, Amneal stated that its ANDA included Paragraph IV certifications with respect to the Patents-in-Suit and alleged that the Patents-in-Suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Product.

27. In the Notice Letter, however, Amneal does not contest infringement of claims 1-6, 8-16, 18-27, 29-40, 42-44, 46-47, 49-51, 53-55, 57-59, and 61-69 of the '446 patent. These claims are variously directed to mannitol esters of a genus of chemical compounds that encompasses bortezomib, the mannitol ester of bortezomib, the lyophilized mannitol ester of bortezomib, a composition comprising mannitol esters of a genus of chemical compounds that encompasses bortezomib and a pharmaceutically-acceptable carrier, a composition comprising the lyophilized mannitol ester of bortezomib and a pharmaceutically acceptable carrier, a lyophilized cake comprising the lyophilized mannitol ester of bortezomib, a composition comprising the mannitol ester of bortezomib and a pharmaceutically acceptable carrier, as well as a method of preparing the lyophilized mannitol ester of bortezomib, a lyophilized cake comprising the lyophilized mannitol ester of bortezomib prepared in accordance with that method, and a composition comprising a pharmaceutically-acceptable carrier and the lyophilized mannitol ester of bortezomib prepared according to that method.

28. In addition, in the Notice Letter Amneal does not contest infringement of claims 1-3, 5-9, 11-17, 19-22, 24-31, 33-36, 38-48, 50-52, 54-55, 57, 59-60, 62-64, 66-68, and 70-78 of the '319 patent. These claims variously encompass mannitol esters of a genus of chemical

compounds that encompasses bortezomib, the mannitol ester of bortezomib, the lyophilized mannitol ester of bortezomib, a composition comprising mannitol esters of a genus of chemical compounds that encompasses bortezomib and a pharmaceutically-acceptable carrier, a composition comprising the lyophilized mannitol ester of bortezomib and a pharmaceutically acceptable carrier, a lyophilized cake comprising the lyophilized mannitol ester of bortezomib, a composition comprising the mannitol ester of bortezomib and a pharmaceutically acceptable carrier, as well as a method of preparing the lyophilized mannitol ester of bortezomib, a lyophilized cake comprising the lyophilized mannitol ester of bortezomib prepared in accordance with that method, and a composition comprising a pharmaceutically-acceptable carrier and the lyophilized mannitol ester of bortezomib prepared according to that method.

29. Amneal has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 210049 under 21 U.S.C. § 355(j)(2), seeking approval to engage in the commercial manufacture, use and/or sale of the Amneal ANDA Product before the expiration of the terms of the Patents-in-Suit.

30. The sale, offer for sale, importation, preparation, and/or use of the proposed Amneal ANDA Product for which Amneal seeks approval in its ANDA will directly and/or indirectly infringe one or more claims of the Patents-in-Suit.

31. Millennium is entitled under 35 U.S.C. § 271(e)(4) to full relief from Amneal's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 210049 relating to the proposed Amneal ANDA Product shall not be earlier than the expiration of the Patents-in-Suit.

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

33. 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.

34. 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.

35. Claims 1-6, 8-16, 18-19, 21-27, 29-30, 32-40, 42-44, 46-47, 50-51, 54-55, 57-59, and 61-69 of the '446 patent are not among the claims of the '446 patent that the Court held invalid.

COUNT I

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

36. Millennium incorporates each of the preceding paragraphs 1-35 as if fully set forth herein.

37. Amneal's submission of ANDA No. 210049 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Amneal 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).

38. Upon information and belief, Amneal intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 210049.

39. The commercial manufacture, use, offer for sale, sale and/or importation of the Amneal ANDA Product would directly infringe one or more claims of the '446 patent. For example, upon information and belief, the Amneal ANDA Product and/or the intended use thereof are covered by at least claims 1-6, 8-16, 18-27, 29-40, 42-44, 46-47, 49-51, 53-55, 57-59, and 61-69 of the '446 patent (the "'446 Asserted Claims").

40. Amneal had knowledge of the '446 patent when it submitted its ANDA to the FDA. Further, upon information and belief, Amneal knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Amneal 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, including *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.*, C.A. No. 12-1011-GMS (consolidated), and Amneal's Notice Letter, which does not contest infringement of claims 1-6, 8-16, 18-27, 29-40, 42-44, 46-47, 49-51, 53-55, 57-59, and 61-69 of the '446 patent.

41. Upon information and belief, use of the Amneal ANDA Product in accordance with and as directed by Amneal's proposed labeling for that product would infringe one or more claims of the '446 patent. For example, upon information and belief, Amneal's proposed labeling will instruct that the Amneal ANDA Product is the lyophilized mannitol ester of bortezomib and will instruct that the Amneal ANDA Product be prepared for administration in a manner covered by at least claims 39-40, 42-44, 46, 50-51, 53-55, 57, 65, and 68 of the '446 patent. Accordingly, Amneal will actively induce infringement under 35 U.S.C. § 271(b) of at least claims 39-40, 42-44, 46, 50-51, 53-55, 57, 65, and 68 of the '446 patent upon approval of ANDA No. 210049.

42. The Amneal ANDA Product is specially made to infringe at least claims 39-40, 42-44, 46, 50-51, 53-55, 57, 63, 65, and 68 of the '446 Patent, and has no substantial non-infringing use. Accordingly, the commercial manufacture, use, offer to sell, sale, or importation of the Amneal ANDA Product will contributorily infringe at least claims 39-40, 42-44, 46, 50-51, 53-55, 57, 63, 65, and 68 of the '446 Patent under 35 U.S.C. § 271(c).

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

44. Unless Amneal is enjoined from directly and indirectly infringing the '446 patent, Millennium will suffer irreparable injury. Millennium has no adequate remedy at law.

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

45. Millennium incorporates each of the preceding paragraphs 1-44 as if fully set forth herein.

46. Amneal's submission of ANDA No. 210049 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Amneal 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).

47. Upon information and belief, Amneal intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 210049.

48. The commercial manufacture, use, offer for sale, sale and/or importation of the Amneal ANDA Product would directly infringe one or more claims of the '319 Patent. For example, upon information and belief, the Amneal ANDA Product and/or the intended use thereof are covered by at least claims 1-3, 5-9, 11-17, 19-22, 24-31, 33-36, 38-48, 50-52, 54-55, 57, 59-60, 62-64, 66-68, and 70-78 of the '319 Patent (the "'319 Asserted Claims").

49. Amneal had knowledge of the '319 Patent when it submitted its ANDA to the FDA. Further, upon information and belief, Amneal knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Amneal 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, including *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.*, C.A. No. 12-1011-GMS (consolidated), and Amneal's Notice Letter, which does not contest infringement of claims 1-3, 5-9, 11-17, 19-22, 24-31, 33-36, 38-48, 50-52, 54-55, 57, 59-60, 62-64, 66-68, and 70-78 of the '319 Patent.

50. Upon information and belief, use of the Amneal ANDA Product in accordance with and as directed by Amneal's proposed labeling for that product would infringe one or more claims of the '319 Patent. For example, upon information and belief, Amneal's proposed labeling will instruct that the Amneal ANDA Product is the lyophilized mannitol ester of bortezomib and will instruct that the Amneal ANDA Product be prepared for administration in a manner covered by at least claims 47-48, 50-52, 54, 59-60, 62-64, 66-67, 70, 72, 74, and 77 of the '319 Patent. Accordingly, Amneal will actively induce infringement under 35 U.S.C. § 271(b) of at least claims 47-48, 50-52, 54, 59-60, 62-64, 66-67, 70, 72, 74, and 77 of the '319 Patent upon approval of ANDA No. 210049.

51. The Amneal ANDA Product is specially made to infringe at least claims 47-48, 50-52, 54, 59-60, 62-64, 66-67, 70, 72, 74, and 77 of the '319 Patent, and has no substantial non-infringing use. Accordingly, the commercial manufacture, use, offer to sell, sale, or importation of the Amneal ANDA Product will contributorily infringe at least claims 47-48, 50-52, 54, 59-60, 62-64, 66-67, 70, 72, 74, and 77 of the '319 Patent under 35 U.S.C. § 271(c).

52. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '319 Patent.

53. Unless Amneal 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 Amneal's submission of ANDA No. 210049 was an act of infringement of the Patents-in-Suit, and that Amneal's manufacture, use, offer to sell, sale, or importation of the Amneal ANDA Product prior to the expiration of the Patents-in-Suit, will infringe and/or actively induce and/or contribute to infringement of the Patents-in-Suit;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Amneal's ANDA No. 210049, or any product or compound that infringes the Patents-in-Suit, shall not be earlier than the expiration of the Patents-in-Suit;

(c) An Order permanently enjoining Amneal, 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 Amneal ANDA Product, or any product or compound that infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit until after the expiration of the Patents-in-Suit;

(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

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