IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
ACTAVIS LLC,	)	
Defendant.	)	

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 Actavis LLC ("Actavis") of New Drug Application ("NDA") No. 208645 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 (the "Patent-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, Actavis is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

4. Upon information and belief, Actavis, 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 NDA No. 208645, Actavis, itself and through its subsidiaries and agents, will make, use, offer to sell, and/or sell the generic products that are the subject of NDA No. 208645 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 Actavis because, among other things, it is a limited liability company organized and existing under the laws of the State of Delaware. Actavis is registered to conduct business in the State of Delaware, Department of State: Division of Corporations, under file number 3996391 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 Actavis 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, Actavis has persistent, systematic and continuous contacts with Delaware as set forth below.

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

11. The court has personal jurisdiction over Actavis 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.

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

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

14. Upon information and belief, Actavis 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.

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

16. Upon information and belief, Actavis will manufacture, market, and/or sell within the United States the generic version of VELCADE® for Injection described in NDA No. 208645 if FDA approval is granted. If NDA No. 208645 is approved, the Actavis 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.

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. Millennium has had an exclusive license to the '446 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 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 Patent.

19. 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.

20. 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.

21. VELCADE® for Injection, and its preparation and use, are covered by one or more claims of the '446 Patent, which has 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."

22. For example, VELCADE® for Injection is 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 10 of the '446 patent. *See e.g.*, '446 patent, claim 10 ("The compound D-mannitol N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate."); *see also* '446 patent, claims 1-6, 8-9, 39-40, 42, 62, 63.

23. By letter dated February 19, 2016 (the "Notice Letter"), Actavis notified Millennium that it had submitted to the FDA NDA No. 208645 for bortezomib for injection, 2.5 mg/ml (2.5 mg/ml; 3.5 mg/1.4 ml), a generic version of VELCADE® for Injection ("the Actavis NDA Product").

24. In the Notice Letter, Actavis stated that its NDA included Paragraph IV certifications with respect to the '446 Patent and alleged that the '446 Patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Actavis NDA Product.

25. In the Notice Letter, however, Actavis does not contest infringement of claims 1-6, 8-10, 39-40, 42, 62, and 63 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, and a composition comprising the mannitol ester of bortezomib and a pharmaceutically acceptable carrier.

26. Actavis has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A) by filing NDA No. 208645 under 21 U.S.C. § 355(b)(2), seeking approval to

engage in the commercial manufacture, use and/or sale of the Actavis NDA Product before the expiration of the terms of the ’446 Patent.

27. The sale, offer for sale, importation, preparation, and/or use of the proposed Actavis NDA Product for which Actavis seeks approval in its NDA will directly and/or indirectly infringe one or more claims of the ’446 Patent.

28. Millennium is entitled under 35 U.S.C. § 271(e)(4) to full relief from Actavis’ acts of infringement, including an Order by this Court ensuring that the effective date of any approval of NDA No. 208645 relating to the proposed Actavis NDA Product shall not be earlier than the expiration of the ’446 Patent.

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

30. 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.

31. 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.

32. Claims 1-6, 8-10, 39-40, 42, 62, and 63 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

33. Millennium incorporates each of the preceding paragraphs 1-32 as if fully set forth herein.

34. Actavis’ submission of NDA No. 208645 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Actavis NDA

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).

35. Upon information and belief, Actavis intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Actavis NDA Product with its proposed labeling immediately and imminently upon approval of NDA No. 208645.

36. The commercial manufacture, use, offer for sale, sale and/or importation of the Actavis NDA Product would directly infringe one or more claims of the ’446 patent. For example, upon information and belief, the Actavis NDA Product is covered by at least claims 1-6, 8-10, 39-40, 42, 62, and 63 of the ’446 patent (the “’446 Asserted Claims”).

37. Actavis had knowledge of the ’446 patent when it submitted its NDA to the FDA. Further, upon information and belief, Actavis knows (or is willfully blind to the fact) that the commercial manufacture, use, offer to sell, sale, or importation of the Actavis NDA 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 Actavis’ Notice Letter, which does not contest infringement of claims 1-6, 8-10, 39-40, 42, 62, and 63 of the ’446 patent.

38. The Actavis NDA 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 Actavis NDA Product will contributorily infringe at least the ’446 Asserted Claims under 35 U.S.C. § 271(c).

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

40. Unless Actavis is enjoined from directly and indirectly infringing the ’446 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 Actavis’ submission of NDA No. 208645 was an act of infringement of the ’446 Patent, and that Actavis’ manufacture, use, offer to sell, sale, or importation of the Actavis NDA Product prior to the expiration of the ’446 Patent, will infringe and/or actively induce and/or contribute to infringement of the ’446 Patent;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Actavis’ NDA No. 208645, or any product or compound that infringes the ’446 Patent, shall not be earlier than the expiration of the ’446 Patent;

(c) An Order permanently enjoining Actavis, 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 Actavis NDA Product, or any product or compound that infringes the ’446 Patent, or inducing or contributing to the infringement of the ’446 Patent until after the expiration of the ’446 Patent;

(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.

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