

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
SUN PHARMACEUTICAL INDUSTRIES)
LIMITED, SUN PHARMA GLOBAL FZE and)
SUN PHARMACEUTICAL INDUSTRIES,)
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 Sun Pharmaceutical Industries Limited (“Sun Ltd.”) of Abbreviated New Drug Application (“ANDA”) No. 208376 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.

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, Defendant Sun Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063. Upon information and belief, Sun Ltd., itself and through its subsidiaries and agents, including Defendants Sun Pharma Global, FZE (“Sun FZE”) and Sun Pharmaceutical Industries, Inc. (“Sun Inc.”), manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Sun FZE is a limited liability company incorporated under the provisions of Shajah’s Emiri Decree Number (2) of 1995, having a principal place of business at Executive Suite 43, Block-Y, SAIF Zone, P.O. Box 122304, Sharjah, U.A.E. Upon information and belief, Sun FZE is a wholly owned subsidiary of Sun Pharma Global Inc., a corporation organized and existing under the laws of the British Virgin Islands, which is in turn a wholly owned subsidiary of Defendant Sun Ltd. Upon information and belief, Sun FZE manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Sun Ltd.

5. Upon information and belief, Defendant Sun Inc. is a corporation organized and existing under the laws of Michigan, with a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512-3605. Upon information and belief, Sun Inc. is registered to conduct business in Delaware, and its registered agent is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Upon information and belief, Sun Inc. holds Delaware Pharmacy – Wholesale license nos. A4-002148, A4-0002109, and A40002107 and Delaware Distributor/Manufacturer CSR license nos. DM-0010549, DM-

0010172, and DM-0010171. Upon information and belief, Sun Inc. manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Sun Ltd and Sun FZE.

6. Upon information and belief, Sun Ltd., Sun FZE, and Sun Inc. (collectively, “Sun”) acted collaboratively in the preparation and submission of ANDA No. 208376.

7. Upon information and belief, following any FDA approval of ANDA No. 208376, Sun Ltd, itself and through its subsidiaries and agents, including Sun FZE and Sun Inc., will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 208376 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

JURISDICTION AND VENUE

8. 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.

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

10. 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. This Court also has personal jurisdiction over the Defendants by virtue of, among other things, their systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. Upon information and belief, Sun Ltd., itself and through its subsidiaries and agents, including Sun FZE and Sun Inc., currently manufactures and distributes for sale dozens of drug products throughout the United States, including in this judicial district.

12. Upon information and belief, Sun Ltd. directs the operations, management and activities of Sun FZE and Sun Inc. in the United States.

13. Upon information and belief, Sun Ltd., directly or through Sun FZE and/or Sun Inc., routinely files ANDAs seeking FDA approval to market its drug products in the United States.

14. Upon information and belief, Sun Ltd., Sun FZE, and Sun Inc. collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in this judicial district.

15. Upon information and belief, Sun FZE and Sun Inc. sell generic drug products in the United States, including in this judicial district, that are manufactured by Sun Ltd.

16. Sun Ltd. and Sun FZE have taken advantage of the jurisdiction of this Court by affirmatively filing counterclaims and requesting entry of judgment in other actions before this Court, including *Astrazeneca AB v. Sun Pharma Global FZE, et al.*, No 14-694-GMS; *Sanofi, et al. v. Sun Pharma Global FZE, et al.*, No 14-cv-294-RGA (D. Del); and *UCB, Inc., et al. v. Sun Pharma Global FZE, et al.*, No. 13-cv-1218-LPS (D. Del.).

17. Sun FZE has also taken advantage of the jurisdiction of this Court by affirmatively filing counterclaims and requesting entry of judgment in other actions before this Court, including *Cephalon, Inc. v. Sun Pharma Global FZE, et al.*, 14-cv-333-GMS; and *Teijin Ltd. v. Sun Pharma Global FZE*, No. 13-cv-1852-SLR (D. Del.).

18. This Court has personal jurisdiction over Sun Inc. by virtue of, among other things, its systematic and continuous contacts with Delaware, including upon information and belief, its status as a corporation registered to conduct business in Delaware and its Delaware Pharmacy – Wholesale and Delaware Distributor/Manufacturer licenses.

19. This Court has personal jurisdiction over Sun Ltd. by virtue of, among other things, its systematic and continuous contacts with Delaware.

20. This Court has personal jurisdiction over Sun FZE by virtue of, among other things, its systematic and continuous contacts with Delaware.

21. In the alternative, this Court may exercise personal jurisdiction over Sun Ltd. and Sun FZE pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. and Sun FZE are foreign companies not subject to personal jurisdiction in the courts of any state; and (c) Sun Ltd. and Sun FZE have 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 Sun Ltd. and Sun FZE satisfies due process.

BACKGROUND

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. VELCADE® for Injection, or its use, is 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."

28. By letter dated May 12, 2015 (the "Notice Letter"), Sun notified Millennium that it had submitted to the FDA ANDA No. 208376 for bortezomib for injection, 3.5 mg/vial, a generic version of VELCADE® for Injection ("the Sun ANDA Product").

29. In the Notice Letters, Sun 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 Sun ANDA Product.

30. This action was commenced before the expiration of forty-five days from the date of Millennium's receipt of the May 12, 2015 Notice Letter.

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

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

32. Sun's submission of ANDA No. 208376 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Sun ANDA Product before the expiration of the '446 patent is an act of infringement of the '446 patent.

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

34. Sun had knowledge of the '446 patent when it submitted its ANDA to the FDA.

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

36. Upon information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208376.

37. Upon information and belief, Sun will actively induce infringement of the '446 patent when ANDA No. 208376 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

38. Upon information and belief, Sun 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.

39. Unless Sun 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

40. Millennium incorporates each of the preceding paragraphs 1 – 39 as if fully set forth herein.

41. Sun's submission of ANDA No. 208376 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Sun ANDA Product before the expiration of the '319 patent is an act of infringement of the '319 patent.

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

43. Sun had knowledge of the '319 patent when it submitted its ANDA to the FDA.

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

45. Upon information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208376.

46. Upon information and belief, Sun will actively induce infringement of the '319 patent when ANDA No. 208376 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

47. Upon information and belief, Sun 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.

48. Unless Sun 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, Millennium prays that this Court grant the following relief:

(a) A judgment that Sun's submission of ANDA No. 208376 was an act of infringement of the '446 and '319 patents, and that Sun's manufacture, use, offer to sell, sale, or importation of the Sun 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 Sun's ANDA No. 208376, 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 Sun, 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 Sun 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.

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