

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS,)
INC.)
)
Plaintiff,)
)
v.) C.A. No. 15-040 (GMS)
)
ONCO THERAPIES LIMITED and AGILA)
SPECIALTIES INC.,)
)
Defendants.)

AMENDED 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 Onco Therapies Limited (“Onco Therapies”) and Agila Specialties Inc. f/k/a Strides Inc. (“Agila,” and collectively with Onco Therapies, “Onco”) of Abbreviated New Drug Application (“ANDA”) No. 205160 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 Onco Therapies Limited is a corporation organized and existing under the laws of India, with its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka India 560076. Upon information and belief, Onco Therapies, itself and through its subsidiaries and agents, including Agila, 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 Agila is a corporation organized and existing under the laws of New Jersey, with its registered office at 201 South Main Street, Suite #3, Lambertville, New Jersey 08530. Upon information and belief, Agila 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 Onco Therapies.

5. Upon information and belief, Onco Therapies and Agila acted collaboratively in the preparation and submission of ANDA No. 205160. Upon information and belief, Onco's preparation and submission of ANDA No. 205160 was done at the direction, under the control, and for the direct benefit of Onco Therapies.

6. Upon information and belief, following any FDA approval of ANDA No. 205160, Onco Therapies, itself and through its subsidiaries and agents, including Agila, will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 205160 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

JURISDICTION AND VENUE

7. 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.

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

9. 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.

10. Upon information and belief, Onco Therapies, itself and through its subsidiaries and agents, including Agila, currently manufactures and distributes for sale dozens of drug products throughout the United States, including in this judicial district.

11. Upon information and belief, Onco Therapies directs the operations, management and activities of Agila in the United States.

12. Upon information and belief, Onco Therapies, directly or through Agila, routinely files ANDAs seeking FDA approval to market its drug products in the United States.

13. Upon information and belief, Onco Therapies and Agila 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.

14. Upon information and belief, Agila sells generic drug products in the United States, including in this judicial district, that are manufactured by Onco Therapies.

15. Onco has 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. Agila Specialties Inc. f/k/a Strides, Inc., et al.*, No. 13-cv-2080-GMS (D. Del.); *Cephalon, Inc. v. Hetero Labs Ltd., et al.*, No. 13-cv-2046-GMS (D. Del.); and *Aventis Pharma S.A. et al v. Strides Inc. et al.*, No. 11-cv-01121-GMS (D. Del.).

16. This Court has personal jurisdiction over Onco Therapies by virtue of, among other things, its systematic and continuous contacts with Delaware.

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

BACKGROUND

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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."

24. By letters dated December 29, 2014 and January 13, 2015 (the "Notice Letters"), Onco notified Millennium that it had submitted to the FDA ANDA No. 205160 for bortezomib for injection, 3.5 mg/vial, a generic version of VELCADE® for Injection ("the Onco ANDA Product").

25. In the Notice Letters, Onco 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 Onco ANDA Product.

26. This action was commenced before the expiration of forty-five days from the date of Millennium's receipt of the December 29, 2014 Notice Letter, and this Amended Complaint is being filed before the expiration of forty-five days from the date of Millennium's receipt of the January 13, 2015 Notice Letter.

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

27. Millennium incorporates each of the preceding paragraphs 1 – 26 as if fully set forth herein.

28. Onco's submission of ANDA No. 205160 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Onco ANDA Product before the expiration of the '446 patent is an act of infringement of the '446 patent.

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

30. Onco had knowledge of the '446 patent when it submitted its ANDA to the FDA.

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

32. Upon information and belief, Onco intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Onco ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205160.

33. Upon information and belief, Onco will actively induce infringement of the '446 patent when ANDA No. 205160 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

34. Upon information and belief, Onco 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.

35. Unless Onco 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

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

37. Onco's submission of ANDA No. 205160 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Onco ANDA Product before the expiration of the '319 patent is an act of infringement of the '319 patent.

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

39. Onco had knowledge of the '319 patent when it submitted its ANDA to the FDA.

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

41. Upon information and belief, Onco intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Onco ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205160.

42. Upon information and belief, Onco will actively induce infringement of the '319 patent when ANDA No. 205160 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

43. Upon information and belief, Onco 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.

44. Unless Onco 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 Onco's submission of ANDA No. 205160 was an act of infringement of the '446 and '319 patents, and that Onco's manufacture, use, offer to sell, sale, or importation of the Onco 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 Onco's ANDA No. 205160, 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 Onco, 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 Onco 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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February 23, 2015

CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 23, 2015, upon the following in the manner indicated:

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