IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, 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 Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL") of Abbreviated New Drug Application ("ANDA") No. 202963 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 DRL Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India. Upon information and belief, DRL Ltd., itself and through its subsidiaries and agents, including DRL 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 DRL Inc. is a corporation organized and existing under the laws of New Jersey, with its registered office at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL 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 DRL Ltd.

5. Upon information and belief, DRL Ltd. and DRL Inc. acted collaboratively in the preparation and submission of ANDA No. 202963. Upon information and belief, DRL's preparation and submission of ANDA No. 202963 was done at the direction, under the control, and for the direct benefit of DRL Ltd.

6. Upon information and belief, following any FDA approval of ANDA No. 202963, DRL Ltd, itself and through its subsidiaries and agents, including DRL Inc., will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202963 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, DRL Ltd., itself and through its subsidiaries and agents, including DRL Inc., currently manufactures and distributes for sale dozens of drug products throughout the United States, including in this judicial district.

11. Upon information and belief, DRL Ltd. directs the operations, management and activities of DRL Inc. in the United States.

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

13. Upon information and belief, DRL Ltd. and DRL 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.

14. Upon information and belief, DRL Inc. sells generic drug products in the United States, including in this judicial district, that are manufactured by DRL Ltd.

15. DRL 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 *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 15-cv-306-GMS (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 15-cv-179 (GMS) (D. Del.); and *Allos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 14-778-RGA (D. Del.).

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

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

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

BACKGROUND

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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."

25. By letter dated May 19, 2015 (the "Notice Letter"), DRL notified Millennium that it had submitted to the FDA ANDA No. 202963 for bortezomib for injection, 3.5 mg/vial, a generic version of VELCADE® for Injection ("the DRL ANDA Product").

26. In the Notice Letters, DRL 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 DRL ANDA Product.

27. This action was commenced before the expiration of forty-five days from the date of Millennium's receipt of the May 19, 2015 Notice Letter.

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

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

29. DRL's submission of ANDA No. 202963 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the DRL ANDA Product before the expiration of the '446 patent is an act of infringement of the '446 patent.

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

31. DRL had knowledge of the '446 patent when it submitted its ANDA to the FDA.

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

33. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 202963.

34. Upon information and belief, DRL will actively induce infringement of the '446 patent when ANDA No. 202963 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

35. Upon information and belief, DRL 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.

36. Unless DRL 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

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

38. DRL's submission of ANDA No. 202963 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the DRL ANDA Product before the expiration of the '319 patent is an act of infringement of the '319 patent.

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

40. DRL had knowledge of the ’319 patent when it submitted its ANDA to the FDA.

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

42. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 202963.

43. Upon information and belief, DRL will actively induce infringement of the ’319 patent when ANDA No. 202963 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

44. Upon information and belief, DRL 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.

45. Unless DRL 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 DRL’s submission of ANDA No. 202963 was an act of infringement of the ’446 and ’319 patents, and that DRL’s manufacture, use, offer to sell, sale, or importation of the DRL 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 DRL's ANDA No. 202963, 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 DRL, 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 DRL 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
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

June 25, 2015