IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| MILLENNIUM PHARMACEUTICALS, INC.<br><br>Plaintiff,<br><br>v.<br><br>ACCORD HEALTHCARE, INC., INTAS BIOPHARMACEUTICALS LTD., and INTAS PHARMACEUTICALS LTD.,<br><br>Defendant. | ) | 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 Accord Healthcare, Inc. of Abbreviated New Drug Application ("ANDA") No. 204405 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of VELCADE® 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. 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 Accord Healthcare, Inc. ("Accord") is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina, 27703.

4. Upon information and belief, Defendant Intas Biopharmaceuticals Ltd. ("Intas Biopharm") is a corporation organized under the laws of India, with its principal place of business at Plot No. 423/P/A, Sarkhej - Bavla Highway, Moraiya, Taluka-Sanand, Ahmedabad 382210, Gujarat, India.

5. Upon information and belief, Defendant Intas Pharmaceuticals Ltd. ("Intas") is a corporation organized under the laws of India, with its principal place of business at Chinubhai Center Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

6. Upon information and belief, Defendant Accord is a wholly-owned subsidiary and agent of Intas.

7. Upon information and belief, Defendant Intas Biopharm is a wholly-owned subsidiary and agent of Intas.

8. Upon information and belief, Intas and Intas Biopharm manufacture, market, and/or sell through Accord various generic drug products for sale and use throughout the United States, including in the State of Delaware.

9. Upon information and belief, the acts of Accord complained of herein were done at the direction of, with the authorization of, and with the cooperation, the assistance, the participation of, and at least in part for the benefit of, Intas and Intas Biopharm.

## JURISDICTION AND VENUE

10. 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.

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

12. The court has personal jurisdiction over Accord because, among other things, Accord markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. Accord has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Millennium, which manufactures VELCADE® for sale and use throughout the United States, including the State of Delaware.

13. Upon information and belief, Accord has previously been sued in this district and has not challenged personal jurisdiction. *See Pfizer Inc. v. Intas Pharms. Ltd. et al*, C.A. No. 11-cv-01253-GMS (D. Del.), *Aventis Pharma S.A. v. Accord Healthcare, Inc. USA.*, C.A. No. 11-cv-00018-GMS (D. Del.). On further information and belief, Accord has also submitted to the jurisdiction of this Court by asserting counterclaims in civil actions initiated in this jurisdiction. *Id.*

14. The court has personal jurisdiction over Intas Biopharm because, among other things, Intas Biopharm markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. Intas Biopharm has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious

action of patent infringement that has led to foreseeable harm and injury to Millennium, which manufactures VELCADE® for sale and use throughout the United States, including the State of Delaware.

15. The court has personal jurisdiction over Intas because, among other things, Intas markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. Intas has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Millennium, which manufactures VELCADE® for sale and use throughout the United States, including the State of Delaware.

16. Upon information and belief, Intas has previously been sued in this district and has not challenged personal jurisdiction. *See Pfizer Inc. v. Intas Pharms. Ltd. et al*, C.A. No. 11-cv-01253-GMS (D. Del.). On further information and belief, Intas has also submitted to the jurisdiction of this Court by asserting counterclaims in civil actions initiated in this jurisdiction. *Id.*

## 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 '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.

20. VELCADE® (bortezomib) 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 who have received at least one prior therapy.

21. Millennium sells VELCADE® in the United States pursuant to New Drug Application No. 21-602 which was approved by the FDA in 2003and 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®, or its use, is covered by one or more claims of the '446 and '319 patents, which have been listed in connection with VELCADE® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

23. By letter dated October 22, 2012, and received October 23, 2012 (the "Notice Letter"), Accord notified Millennium that it had submitted to the FDA ANDA No. 204405 for Bortezomib for Injection, 3.5 mg/vial, a generic version of VELCADE® ("the Accord ANDA Product").

24. Upon information and belief, Intas Biopharm actively and knowingly directed, induced, participated in, assisted with, contributed to, and/or aided and abetted the submission to the FDA of ANDA No. 204405.

25. Upon information and belief, Intas actively and knowingly directed, induced, participated in, assisted with, contributed to, and/or aided and abetted the submission to the FDA of ANDA No. 204405.

26. In the Notice Letter, Accord 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, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Accord ANDA Product.

27. This action is being commenced before the expiration of forty-five days from the date of Plaintiff's receipt of the Notice Letter.

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

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

29. Defendants' submission of ANDA No. 204405 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Accord 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 Accord ANDA Product would infringe one or more claims of the '446 patent.

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

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

33. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 204405.

34. Upon information and belief, Defendants will actively induce infringement of the '446 patent when ANDA No. 204405 is approved, and plan and intend to, and will do so immediately and imminently upon approval.

35. Upon information and belief, Defendants 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 Defendants are 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. Plaintiff incorporates each of the preceding paragraphs 1 – 36 as if fully set forth herein.

38. Defendants' submission of ANDA No. 204405 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Accord 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 Accord ANDA Product would infringe one or more claims of the '319 patent.

40. Defendants had knowledge of the '319 patent when it submitted its ANDA to the FDA.

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

42. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 204405.

43. Upon information and belief, Defendants will actively induce infringement of the '319 patent when ANDA No. 204405 is approved, and plan and intend to, and will do so immediately and imminently upon approval.

44. Upon information and belief, Defendants 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 Defendants are 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, Plaintiff prays that this Court grant the following relief:

(a) A judgment that Defendants' submission of ANDA No. 204405 was an act of infringement of the '446 and '319 patents, and that Defendants' manufacture, use, offer to

sell, sale, or importation of the Accord 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 Defendants' ANDA No. 204405, 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 Defendants, and their 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 Accord 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 Plaintiff 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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