

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., and)
MILLENNIUM PHARMACEUTICALS,)
INC.,)

Plaintiff,)

v.)

C.A. No. _____)

BEN VENUE LABORATORIES, INC. d/b/a)
BEDFORD LABORATORIES,)

Defendant.)

COMPLAINT

Plaintiffs Millennium Pharmaceuticals, Inc. and Merck Sharp & Dohme Corp., by their attorneys, hereby allege 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 Ben Venue Laboratories, Inc. (“Ben Venue”), d/b/a Bedford Laboratories, of Abbreviated New Drug Application (“ANDA”) No. 205058 with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell generic versions of INTEGRILIN[®] prior to the expiration of U.S. Patent Nos. 5,807,825, and 5,747,447 and 5,968,902.

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.

3. Plaintiff Merck Sharp & Dohme Corp. (“MSD Corp.”) is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 1 Merck Drive, Whitehouse Station, New Jersey 08889. MSD Corp. is a wholly-owned subsidiary of Merck & Co., Inc., a corporation organized and existing under the laws of the State of New Jersey. MSD Corp. is successor to Schering Corporation (“Schering”).

4. Upon information and belief, Ben Venue is a corporation organized and existing under the laws of Delaware, with its principal place of business at 300 Northfield Road, Bedford, Ohio 44146, and Bedford Laboratories (“Bedford”) is a division of Ben Venue. Upon information and belief, Ben Venue d/b/a Bedford is in the business of developing, manufacturing, marketing, and selling generic drugs.

JURISDICTION AND VENUE

5. 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 and 1338(a).

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

7. Ben Venue is subject to personal jurisdiction in Delaware because, among other things, it is a resident and citizen of the State of Delaware and has submitted to the jurisdiction of courts in Delaware by virtue of Ben Venue’s incorporation under Delaware law. Ben Venue is also subject to personal jurisdiction in Delaware because, among other things, it manufactures, markets, and 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.

BACKGROUND

8. INTEGRILIN[®] is an antithrombotic agent that reversibly inhibits platelet aggregation by preventing binding of fibrinogen to the glycoprotein IIb-IIIa receptor. INTEGRILIN[®] is indicated for the treatment of patients with acute coronary syndrome, including patients who are to be managed medically and those undergoing percutaneous coronary intervention, including intracoronary stenting.

9. MSD Corp., as successor to Schering, sells INTEGRILIN[®] in the United States pursuant to a New Drug Application that has been approved by the FDA.

10. United States Patent No. 5,807,825 (“the ’825 patent”), entitled “Platelet Aggregation Inhibitors” (Exhibit A), was duly and legally issued on September 15, 1998. The ’825 patent is owned by Millennium and exclusively licensed to MSD Corp.

11. United States Patent No. 5,747,447 (“the ’447 patent”), entitled “Stable Polypeptide Composition” (Exhibit B), was duly and legally issued on May 5, 1998. The ’447 patent is owned by Millennium and exclusively licensed to MSD Corp.

12. United States Patent No. 5,968,902 (“the ’902 patent”), entitled “Platelet Aggregation Inhibitors” (Exhibit C), was duly and legally issued on October 19, 1999. The ’902 patent is owned by Millennium and exclusively licensed to MSD Corp.

13. INTEGRILIN[®] and its use are covered by one or more claims of each of the ’825, ’447 and ’902 patents, and those patents have been listed in connection with INTEGRILIN[®] in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

14. By letter dated August 12, 2013 (the “Notice Letter”), Bedford notified Millennium and Merck & Co., Inc. that it had submitted to the FDA ANDA No. 205058 for

eptifibatide injection, 2 mg/mL, 10 mL and 100 mL vials and eptifibatide injection, 0.75 mg/mL, 100 mL vials, drug products that are generic versions of INTEGRILIN[®] (“Bedford’s ANDA Products”). The purpose of the submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Bedford’s ANDA Products prior to the expiration of the ’825, ’447 and ’902 patents.

15. In the Notice Letter, Bedford also notified Millennium and Merck & Co., Inc. that, as a part of its ANDAs, Bedford had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’825, ’447 and ’902 patents. Upon information and belief, Bedford submitted ANDA No. 205058 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) asserting that the ’825, ’447 and ’902 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Bedford’s ANDA Products.

16. This action is being commenced before the expiration of forty-five days from the date of the Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 5,807,825

17. Plaintiffs incorporate each of the proceeding paragraphs 1 - 16 as if fully set forth herein.

18. The use of Bedford’s ANDA Products is covered by one or more claims of the ’825 patent. Bedford did not assert in the Notice Letter noninfringement of any of the claims of the ’825 patent.

19. Bedford had knowledge of the ’825 patent when it submitted its ANDA.

20. Bedford's filing of ANDA No. 205058 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Bedford's ANDA Products before the expiration of the '825 patent was an act of infringement of the '825 patent.

21. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's ANDA Products would infringe one or more claims of the '825 patent.

22. Upon information and belief, use of Bedford's ANDA Products in accordance with and as directed by Bedford's proposed labeling for those products would infringe one or more claims of the '825 patent.

23. Upon information and belief, Bedford intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 205058.

24. Upon information and belief, Bedford plans and intends to, and will, actively induce infringement of the '825 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

25. Upon information and belief, Bedford knows that Bedford's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '825 patent, and that Bedford's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Bedford plans and intends to, and will, contribute to the infringement of the '825 patent immediately and imminently upon approval of ANDA No. 205058.

26. The foregoing actions by Bedford constitute and/or will constitute infringement of the '825 patent, active inducement of infringement of the '825 patent, and/or contribution to the infringement by others of the '825 patent.

27. Upon information and belief, Bedford acted without a reasonable basis for believing that it would not be liable for infringing the '825 patent, actively inducing infringement of the '825 patent, and/or contributing to the infringement by others of the '825 patent.

28. Unless Bedford is enjoined from infringing the '825 patent, actively inducing infringement of the '825 patent, and/or contributing to the infringement by others of the '825 patent, Millennium and MSD Corp. will suffer irreparable injury. Millennium and MSD Corp. have no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 5,747,447

29. Plaintiffs incorporate each of the proceeding paragraphs 1 - 28 as if fully set forth herein.

30. The use of Bedford's ANDA Products is covered by one or more claims of the '447 patent.

31. Bedford had knowledge of the '447 patent when it submitted its ANDA.

32. Bedford's filing of ANDA No. 205058 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Bedford's ANDA Products before the expiration of the '447 patent was an act of infringement of the '447 patent.

33. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's ANDA Products would infringe one or more claims of the '447 patent.

34. Upon information and belief, use of Bedford's ANDA Products in accordance with and as directed by Bedford's proposed labeling for those products would infringe one or more claims of the '447 patent.

35. Upon information and belief, Bedford intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 205058.

36. Upon information and belief, Bedford plans and intends to, and will, actively induce infringement of the '447 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. Upon information and belief, Bedford knows that Bedford's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '447 patent, and that Bedford's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Bedford plans and intends to, and will, contribute to the infringement of the '447 patent immediately and imminently upon approval of ANDA No. 205058.

38. The foregoing actions by Bedford constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and/or contribution to the infringement by others of the '447 patent.

39. Upon information and belief, Bedford acted without a reasonable basis for believing that it would not be liable for infringing the '447 patent, actively inducing infringement of the '447 patent, and/or contributing to the infringement by others of the '447 patent.

40. Unless Bedford is enjoined from infringing the '447 patent, actively inducing infringement of the '447 patent, and/or contributing to the infringement by others of the '447 patent, Millennium and MSD Corp. will suffer irreparable injury. Millennium and MSD Corp. have no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 5,968,902

41. Plaintiffs incorporate each of the proceeding paragraphs 1 - 40 as if fully set forth herein.

42. The use of Bedford's ANDA Products is covered by one or more claims of the '902 patent. Bedford did not assert in the Notice Letter noninfringement of any of the claims of the '902 patent.

43. Bedford had knowledge of the '902 patent when it submitted its ANDA.

44. Bedford's filing of ANDA No. 205058 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Bedford's ANDA Products before the expiration of the '902 patent was an act of infringement of the '902 patent.

45. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's ANDA Products would infringe one or more claims of the '902 patent.

46. Upon information and belief, use of Bedford's ANDA Products in accordance with and as directed by Bedford's proposed labeling for those products would infringe one or more claims of the '902 patent.

47. Upon information and belief, Bedford intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Bedford's

ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 205058.

48. Upon information and belief, Bedford plans and intends to, and will, actively induce infringement of the '902 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

49. Upon information and belief, Bedford knows that Bedford's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '902 patent, and that Bedford's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Bedford plans and intends to, and will, contribute to the infringement of the '902 patent immediately and imminently upon approval of ANDA No. 205058.

50. The foregoing actions by Bedford constitute and/or will constitute infringement of the '902 patent, active inducement of infringement of the '902 patent, and/or contribution to the infringement by others of the '902 patent.

51. Upon information and belief, Bedford acted without a reasonable basis for believing that it would not be liable for infringing the '902 patent, actively inducing infringement of the '902 patent, and/or contributing to the infringement by others of the '902 patent.

52. Unless Bedford is enjoined from infringing the '902 patent, actively inducing infringement of the '902 patent, and/or contributing to the infringement by others of the '902 patent, Millennium and MSD Corp. will suffer irreparable injury. Millennium and MSD Corp. have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(a) A judgment that the '825, '447 and '902 patents are infringed by Bedford's ANDA Products, that Bedford's submission of ANDA No. 205058 was an act of infringement of those patents, and that Bedford's making, using, offering to sell, selling, marketing, distributing, or importing Bedford's ANDA Products, or any product or compound that infringes the '825, '447 and '902 patents, prior to the expiration of those patents, will infringe, actively induce infringement, and contribute to the infringement of those patents.

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Bedford's ANDA No. 205058, or any product or compound that infringes the '825, '447 and '902 patents, shall be a date which is not earlier than the expiration of those patents;

(c) An Order permanently enjoining Bedford, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Bedford's ANDA Products, or any product or compound that infringes the '825, '447 and '902 patents, or inducing or contributing to the infringement of the '825, '447 and '902 patents until after the expiration of those patents;

(d) Damages or other monetary relief if Bedford engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Bedford's ANDA Products, or any product or compound that infringes the '825, '447 and '902 patents, or the inducement or contribution of the foregoing, prior to the expiration of those patents.

(e) A declaration that this is an exceptional case and an award of attorneys' fees to plaintiffs pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' reasonable costs; and

(g) Such other and further relief as this Court deems just and proper.

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