IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., and MILLENNIUM PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
APP PHARMACEUTICALS, INC., APP PHARMACEUTICALS, LLC, FRESENIUS KABI PHARMACEUTICALS HOLDING, INC., FRESENIUS KABI USA, INC., and FRESENIUS KABI USA, LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Millennium Pharmaceuticals, Inc. and Merck Sharp & Dohme Corp. (collectively, "Plaintiffs"), 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 APP Pharmaceuticals, LLC, now known as Fresenius Kabi USA, LLC, of an amendment to Abbreviated New Drug Application ("ANDA") No. 204361 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of INTEGRILIN® prior to the expiration of U.S. Patent Nos. 5,807,825, 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"), a former New Jersey corporation.

4. Upon information and belief, Defendant Fresenius Kabi Pharmaceuticals Holding, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at Else-Kroener-Strasse 1, 61352 Bad Homburg v.d.H., Germany. Upon information and belief, Fresenius Kabi Pharmaceuticals Holding, Inc. is in the business of developing, manufacturing, marketing, and selling generic drugs. Upon information and belief, the business of Fresenius Kabi Pharmaceuticals Holding, Inc. consists exclusively of that of Defendant Fresenius Kabi USA, Inc., its wholly-owned, operating subsidiary, which develops, manufactures, distributes, markets, and sells its generic drug products throughout the United States.

5. Upon information and belief, Defendant Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Upon information and belief, Fresenius Kabi USA, Inc. is a wholly-owned subsidiary of Fresenius Kabi Pharmaceuticals Holding, Inc. and is controlled and/or dominated by Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, Fresenius Kabi USA, Inc. itself and through its wholly-owned subsidiary and agent Defendant Fresenius Kabi USA, LLC, develops, manufactures, and/or distributes generic drugs for sale and use throughout the United

States at the direction, under the control, and for the direct benefit of Fresenius Kabi Pharmaceuticals Holding, Inc.

6. Upon information and belief, Defendant APP Pharmaceuticals, Inc. was a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Upon information and belief, APP Pharmaceuticals, Inc. was a wholly-owned subsidiary of Fresenius Kabi Pharmaceuticals Holding, Inc. and was controlled and/or dominated by Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, APP Pharmaceuticals, Inc. itself and through its wholly-owned subsidiary and agent APP Pharmaceuticals, LLC, developed, manufactured, and/or distributed numerous generic drugs for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, APP Pharmaceuticals, Inc. is now known as Fresenius Kabi USA, Inc.

7. Upon information and belief, Defendant Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Upon information and belief, Fresenius Kabi USA, LLC is a wholly-owned subsidiary of Fresenius Kabi USA, Inc. Upon information and belief, Fresenius Kabi USA, LLC is controlled and/or dominated by Fresenius Kabi USA, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, Fresenius Kabi USA, LLC develops, manufactures, and/or distributes generic drug products for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Fresenius Kabi USA, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc.

8. Upon information and belief, Defendant APP Pharmaceuticals, LLC was a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Upon information and belief, APP Pharmaceuticals, LLC was a wholly-owned subsidiary of APP Pharmaceuticals, Inc. Upon information and belief, APP Pharmaceuticals, LLC was controlled and/or dominated by APP Pharmaceuticals, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, APP Pharmaceuticals, LLC developed, manufactured, and/or distributed generic drug products for sale and use throughout the United States at the direction, under the control, and for the direct benefit of APP Pharmaceuticals, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, APP Pharmaceuticals, LLC is now known as Fresenius Kabi USA, LLC.

9. Upon information and belief, APP Pharmaceuticals, LLC acted as an agent for its successor, Fresenius Kabi USA, LLC; APP Pharmaceuticals, Inc. and its successor, Fresenius Kabi USA, Inc.; and Fresenius Kabi Pharmaceuticals Holding, Inc. for purposes including, but not limited to, making regulatory submissions to the FDA relating to generic injectable products. Upon information and belief, APP Pharmaceuticals, LLC's preparation and submission of an amendment to ANDA No. 204361 was done at the direction, under the control, and for the direct benefit of Fresenius Kabi USA, LLC, APP Pharmaceuticals, Inc., Fresenius Kabi USA, Inc., and Fresenius Kabi Pharmaceuticals Holding, Inc. Upon information and belief, Fresenius Kabi USA, LLC, APP Pharmaceuticals, Inc., Fresenius Kabi USA, Inc., and Fresenius Kabi Pharmaceuticals Holding, Inc. directed APP Pharmaceuticals, LLC to submit an amendment to ANDA No. 204361, in whole or in part, in an attempt to shield Fresenius Kabi

USA, LLC, APP Pharmaceuticals, Inc., Fresenius Kabi USA, Inc., and Fresenius Kabi Pharmaceuticals Holding, Inc. from liability for patent infringement based upon that act.

10. Defendants Fresenius Kabi Pharmaceuticals Holding, Inc., Fresenius Kabi USA, Inc., Fresenius Kabi USA, LLC, APP Pharmaceuticals, Inc., and APP Pharmaceuticals, LLC are collectively referred to hereafter as "Fresenius Kabi / APP."

JURISDICTION AND VENUE

11. 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.

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

13. All of the Defendants are subject to personal jurisdiction in Delaware because, among other things, they are residents and citizens of the State of Delaware and have submitted themselves to the jurisdiction of courts in Delaware by virtue of their incorporation or organization under Delaware law. The Defendants are also subject to personal jurisdiction in Delaware because, among other things, they each directly and/or through wholly-owned subsidiaries, manufacture, market, and sell generic drugs throughout the United States and within the State of Delaware and therefore purposefully avail themselves of the privilege of conducting activities within the State of Delaware. In addition, because APP Pharmaceuticals, Inc. and APP Pharmaceuticals, LLC consented to jurisdiction in this district in previous litigations by affirmatively filing counterclaims, this Court has personal jurisdiction over Defendants APP Pharmaceuticals, Inc.; APP Pharmaceuticals, LLC; Fresenius Kabi USA, Inc., as successor to

APP Pharmaceuticals, Inc.; and Fresenius Kabi USA, LLC, as successor to APP Pharmaceuticals, LLC.

BACKGROUND

14. 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.

15. 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.

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

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

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

19. INTEGRILIN® and the use of INTEGRILIN® is covered by one or more claims of the '825, '447 and '902 patents, and the '825, '447 and '902 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."

20. Upon information and belief, APP Pharmaceuticals, LLC submitted to the FDA ANDA Nos. 204361 and 204362 as well as an amendment to ANDA No. 204361.

21. By letter dated September 25, 2012 (the "First Notice Letter"), APP Pharmaceuticals, LLC notified Millennium, Schering (now MSD Corp.), and Merck & Co., Inc. that it had submitted to the FDA ANDA Nos. 204361 and 204362 for Fresenius Kabi / APP's Eptifibatide, Injection, 2 mg/mL, 10 mL vial and Eptifibatide, Injection, 0.75 mg/mL, 100 mL vial, drug products that are generic versions of INTEGRILIN®. 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 these products prior to the expiration of the '825, '447 and '902 patents.

22. In the First Notice Letter, APP Pharmaceuticals, LLC also notified Millennium, Schering (now MSD Corp.), and Merck & Co., Inc. that, as a part of its ANDAs, APP Pharmaceuticals, LLC 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) ("Paragraph IV certifications") 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 the products listed in ANDA Nos. 204361 and 204362.

23. On November 9, 2012, less than forty-five days from the date of the First Notice Letter, Plaintiffs brought an action for patent infringement against Fresenius Kabi / APP that is currently pending in this Court as Civil Action No. 1:12-cv-01410-RGA.

24. By letter dated December 21, 2012 (the "Second Notice Letter"), APP Pharmaceuticals, LLC notified Millennium and MSD Corp. that it had submitted to the FDA an amendment to ANDA No. 204361 ("amended ANDA No. 204361") to include an additional

drug product that is a generic version of INTEGRILIN®, namely Fresenius Kabi / APP's Eptifibatide, Injection, 2 mg/mL, 100 mL vial ("Fresenius Kabi / APP's ANDA Product"). The purpose of the submission of amended ANDA No. 204361 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius Kabi / APP's ANDA Product prior to the expiration of the '825, '447 and '902 patents.

25. In the Second Notice Letter, APP Pharmaceuticals, LLC also notified Millennium and MSD Corp. that, as a part of amended ANDA No. 204361, APP Pharmaceuticals, LLC had filed Paragraph IV certifications with respect to the '825, '447 and '902 patents with respect to the 2mg/mL, 100mL vial product. Upon information and belief, APP Pharmaceuticals, LLC submitted amended ANDA No. 204361 to the FDA containing Paragraph IV certifications 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 Fresenius Kabi / APP's ANDA Product.

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

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

27. Plaintiffs incorporate each of the proceeding paragraphs 1 - 26 as if fully set forth herein.

28. The use of Fresenius Kabi / APP's ANDA Product is covered by one or more claims of the '825 patent.

29. Fresenius Kabi / APP had knowledge of the '825 patent when it submitted its amended ANDA No. 204361.

30. Fresenius Kabi / APP's filing of amended ANDA No. 204361 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius Kabi / APP's ANDA Product before the expiration of the '825 patent is an act of infringement of the '825 patent.

31. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product would infringe one or more claims of the '825 patent.

32. Upon information and belief, use of Fresenius Kabi / APP's ANDA Product in accordance with and as directed by Fresenius Kabi / APP's proposed labeling for this product would infringe one or more claims of the '825 patent.

33. Upon information and belief, Fresenius Kabi / APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product with its proposed labeling immediately and imminently upon approval of amended ANDA No. 204361.

34. Upon information and belief, Fresenius Kabi / APP plans and intends to, and will, actively induce infringement of the '825 patent when its amended ANDA No. 204361 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

35. Upon information and belief, Fresenius Kabi / APP knows that Fresenius Kabi / APP's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '825 patent, and that Fresenius Kabi / APP's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief,

Fresenius Kabi / APP plans and intends to, and will, contribute to the infringement of the '825 patent immediately and imminently upon approval of amended ANDA No. 204361.

36. The foregoing actions by Fresenius Kabi / APP 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.

37. Upon information and belief, Fresenius Kabi / APP 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.

38. Unless Fresenius Kabi / APP 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

39. Plaintiffs incorporate each of the proceeding paragraphs 1 - 38 as if fully set forth herein.

40. The use of Fresenius Kabi / APP's ANDA Product is covered by one or more claims of the '447 patent.

41. Fresenius Kabi / APP had knowledge of the '447 patent when it submitted its amended ANDA No. 204361.

42. Fresenius Kabi / APP's filing of amended ANDA No. 204361 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale,

and/or sale of Fresenius Kabi / APP's ANDA Product before the expiration of the '447 patent is an act of infringement of the '447 patent.

43. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product would infringe one or more claims of the '447 patent.

44. Upon information and belief, use of Fresenius Kabi / APP's ANDA Product in accordance with and as directed by Fresenius Kabi / APP's proposed labeling for this product would infringe one or more claims of the '447 patent.

45. Upon information and belief, Fresenius Kabi / APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product with its proposed labeling immediately and imminently upon approval of amended ANDA No. 204361.

46. Upon information and belief, Fresenius Kabi / APP plans and intends to, and will, actively induce infringement of the '447 patent when its amended ANDA No. 204361 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. Upon information and belief, Fresenius Kabi / APP knows that Fresenius Kabi / APP's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent, and that Fresenius Kabi / APP's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi / APP plans and intends to, and will, contribute to the infringement of the '447 patent immediately and imminently upon approval of amended ANDA No. 204361.

48. The foregoing actions by Fresenius Kabi / APP 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.

49. Upon information and belief, Fresenius Kabi / APP 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.

50. Unless Fresenius Kabi / APP 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

51. Plaintiffs incorporate each of the proceeding paragraphs 1 - 50 as if fully set forth herein.

52. The use of Fresenius Kabi / APP's ANDA Product is covered by one or more claims of the '902 patent.

53. Fresenius Kabi / APP had knowledge of the '902 patent when it submitted its amended ANDA No. 204361.

54. Fresenius Kabi / APP's filing of amended ANDA No. 204361 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius Kabi / APP's ANDA Product before the expiration of the '902 patent is an act of infringement of the '902 patent.

55. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product would infringe one or more claims of the '902 patent.

56. Upon information and belief, use of Fresenius Kabi / APP's ANDA Product in accordance with and as directed by Fresenius Kabi / APP's proposed labeling for this product would infringe one or more claims of the '902 patent.

57. Upon information and belief, Fresenius Kabi / APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Fresenius Kabi / APP's ANDA Product with its proposed labeling immediately and imminently upon approval of amended ANDA No. 204361.

58. Upon information and belief, Fresenius Kabi / APP plans and intends to, and will, actively induce infringement of the '902 patent when its amended ANDA No. 204361 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

59. Upon information and belief, Fresenius Kabi / APP knows that Fresenius Kabi / APP's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '902 patent, and that Fresenius Kabi / APP's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi / APP plans and intends to, and will, contribute to the infringement of the '902 patent immediately and imminently upon approval of amended ANDA No. 204361.

60. The foregoing actions by Fresenius Kabi / APP 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.

61. Upon information and belief, Fresenius Kabi / APP 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.

62. Unless Fresenius Kabi / APP 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 Fresenius Kabi / APP's ANDA Product, that Fresenius Kabi / APP's submission of amended ANDA No. 204361 is an act of infringement of the '825, '447 and '902 patents, and that Fresenius Kabi / APP's making, using, offering to sell, selling, marketing, distributing, or importing Fresenius Kabi / APP's ANDA Product, or any product or compound that infringes the '825, '447 and '902 patents, prior to the expiration of the '825, '447 and '902 patents, will infringe, actively induce infringement, and contribute to the infringement of the '825, '447 and '902 patents.

(b) A declaration that the '825, '447 and '902 patents are valid and enforceable;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius Kabi / APP's amended ANDA No. 204361, 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 the '825, '447 and '902 patents;

(d) An Order permanently enjoining Fresenius Kabi / APP, 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 Fresenius Kabi / APP's ANDA Product, 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 the '825, '447 and '902 patents;

(e) Damages or other monetary relief if Fresenius Kabi / APP engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Fresenius Kabi / APP's ANDA Product, 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 '825, '447 and '902 patents.

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

(g) Plaintiffs' reasonable costs of suit incurred; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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 Plaintiffs Merck Sharp & Dohme Corp. and Millennium Pharmaceuticals, Inc.

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Kerry Begley
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000

January 31, 2013