IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC .,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 13-467-GMS
v.	)	
	)	
FRESENIUS KABI USA, LLC, FRESENIUS KABI USA, INC., and FRESENIUS KABI PHARMACEUTICALS HOLDING, INC.,	)	
	)	
Defendants.	)	

FRESENIUS KABI USA, LLC'S, FRESENIUS KABI USA, INC.'S, AND FRESENIUS KABI PHARMACEUTICALS HOLDING, INC.'S ANSWER AND FRESENIUS KABI USA, LLC'S COUNTERCLAIM

Defendants Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc. and Fresenius Kabi Pharmaceuticals Holding, Inc. (collectively, "Fresenius") hereby respond to Millennium Pharmaceuticals, Inc.'s ("Millennium") Complaint as follows:

NATURE OF THE ACTION

1. Fresenius admits that Millennium purports to bring this action under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent Nos. 6,713,446 ("the '446 patent") and 6,958,319 ("the '319 patent") related to Fresenius' New Drug Application ("NDA") No. 205004 with the U.S. Food and Drug Administration ("FDA"). Fresenius denies the remaining allegations in Paragraph 1.

2. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and therefore denies the same.

3. Fresenius admits that Fresenius Kabi Pharmaceuticals Holding, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of

business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Fresenius denies the remaining allegations in Paragraph 3.

4. Fresenius admits that Fresenius Kabi USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Fresenius admits that Fresenius Kabi, USA, Inc. is a wholly-owned subsidiary of Fresenius Kabi Pharmaceuticals Holding, Inc. Fresenius denies the remaining allegations in Paragraph 4.

5. Fresenius admits that Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173. Fresenius admits that Fresenius Kabi, USA, LLC is a wholly-owned subsidiary of Fresenius Kabi USA, Inc. Fresenius admits that Fresenius Kabi USA, LLC sells drug products in the United States. Fresenius denies the remaining allegations in Paragraph 5.

6. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6 and therefore denies the same.

JURISDICTION AND VENUE

7. Fresenius admits that Millennium purports to bring this action under the patent laws of the United States. Fresenius admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Fresenius admits, for the purposes of this action only, that venue is proper with respect to Fresenius Kabi USA, LLC in this judicial district. Fresenius denies that venue is proper with respect to Fresenius Kabi Pharmaceuticals Holding, Inc. or Fresenius Kabi USA, Inc. in this judicial district pursuant to 28 U.S.C. §§ 1391 or 1400(b).

9. To the extent that Paragraph 9 states conclusions of law, no response is required from Fresenius. Fresenius admits, for the purposes of this action only, that this Court has personal jurisdiction over Fresenius Kabi USA, LLC. Fresenius denies that this Court has personal jurisdiction in this action over Fresenius Kabi Pharmaceuticals Holding, Inc. or Fresenius Kabi USA, Inc.

10. To the extent that Paragraph 10 states conclusions of law, no response is required from Fresenius. Fresenius admits that Fresenius Kabi USA, LLC sells drug products in the United States and is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesaler" of drug products. Fresenius denies the remaining allegations in Paragraph 10.

BACKGROUND

11. Fresenius admits that the '446 patent is titled "Formulation of Boronic Acid Compounds" and states on its face that it issued on March 30, 2004. Fresenius admits that what appears to be a copy of the '446 patent is attached to the Complaint as Exhibit A. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 11 and therefore denies the same.

12. Fresenius admits that the '319 patent is titled "Formulation of Boronic Acid Compounds" and states on its face that it issued on October 25, 2005. Fresenius admits that what appears to be a copy of the '319 patent is attached to the Complaint as Exhibit B. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 12 and therefore denies the same.

13. Fresenius lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 13 and therefore denies the same.

14. Fresenius admits that VELCADE® is 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. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 14 and therefore denies the same.

15. Fresenius admits that Millennium is the holder of NDA No. 21-602. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 15 and therefore denies the same.

16. Fresenius admits that Millennium caused the FDA to list the '446 and '319 patents for the product VELCADE® in the Orange Book. To the extent that Paragraph 16 states conclusions of law, no response is required from Fresenius. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 16 and therefore denies the same.

17. Fresenius admits that Fresenius Kabi USA, LLC sent a letter dated February 5, 2013 to Millennium notifying Millennium that Fresenius Kabi USA, LLC had submitted an NDA for bortezomib injectable, 3.5 mg/vial ("the Fresenius NDA Product") to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Fresenius admits that the FDA assigned NDA No. 205004 to the application. Upon information and belief, Fresenius admits that Millennium received the letter on February 6, 2013.

18. Fresenius admits the allegations in Paragraph 18.

19. Fresenius lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 19 and therefore denies the same.

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

20. Fresenius incorporates by reference its responses to Paragraphs 1-19 as if fully set forth herein.

21. To the extent that Paragraph 21 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 21.

22. Fresenius denies the allegations in Paragraph 22.

23. Fresenius admits that Fresenius Kabi USA, LLC had knowledge of the '446 patent when Fresenius Kabi USA, LLC submitted its NDA to the FDA. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 23 and therefore denies the same.

24. Fresenius denies the allegations in Paragraph 24.

25. Fresenius lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 25 and therefore denies the same.

26. Fresenius denies the allegations in Paragraph 26.

27. Fresenius denies the allegations in Paragraph 27.

28. To the extent that Paragraph 28 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 28.

COUNT II
ALLEGED INFRINGEMENT OF U.S. PATENT NO. 6,958,319

29. Fresenius incorporates by reference its responses to Paragraphs 1-28 as if fully set forth herein.

30. To the extent that Paragraph 30 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 30.

31. Fresenius denies the allegations in Paragraph 31.

32. Fresenius admits that Fresenius Kabi USA, LLC had knowledge of the '319 patent when Fresenius Kabi USA, LLC submitted its NDA to the FDA. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 32 and therefore denies the same.

33. Fresenius denies the allegations in Paragraph 33.

34. Fresenius lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 34 and therefore denies the same.

35. Fresenius denies the allegations in Paragraph 35.

36. Fresenius denies the allegations in Paragraph 36.

37. To the extent that Paragraph 37 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 37.

PRAYER FOR RELIEF

38. Fresenius denies each and every allegation in the Complaint not expressly admitted above.

39. Fresenius denies that the Plaintiff is entitled to the judgment and relief prayed for in paragraphs (a) through (e) of the Complaint.

DEFENSES

First Defense (Failure to state a claim)

40. Millennium's Complaint fails to state a claim upon which relief can be granted.

Second Defense (Failure to join a necessary party)

41. Millennium's claims are barred because it has failed to join a necessary or indispensable party.

Third Defense (Lack of standing)

42. Millennium's claims are barred because Millennium lacks substantial rights in the '446 or '319 patents necessary to assert and maintain claims of patent infringement in its own capacity with respect to the '446 or '319 patents.

Fourth Defense (Invalidity)

43. One or more claims of the '446 and '319 patents are invalid because they do not comply with one or more of the requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.* including, without limitation, those identified in 35 U.S.C. §§ 101-103, 112, 116, or for obviousness-type double patenting.

Fifth Defense (Non-infringement)

44. Fresenius is not infringing, has not infringed, and will not infringe any valid and enforceable claim of the '446 or '319 patents, either literally or under the doctrine of equivalents.

Sixth Defense (Prosecution history estoppel)

45. Any claim by Millennium that a claim of the '446 or '319 patents covers and includes the Fresenius NDA Product is barred by the doctrine of prosecution history estoppel or otherwise by virtue of admissions, amendments, arguments, representations or misrepresentations made to the USPTO during the prosecution of the applications that issued as the '446 and '319 patents.

Seventh Defense (No costs)

46. Millennium is barred by 35 U.S.C. § 288 from recovering any costs related to this suit.

COUNTERCLAIM FOR A DECLARATORY JUDGMENT

Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC, for its counterclaim against Plaintiff-Counterclaim Defendant Millennium Pharmaceuticals, Inc., alleges as follows:

NATURE OF THE ACTION

47. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC, repeats and incorporates by reference its responses to Paragraphs 1-37 and the Prayer for Relief of Millennium's Complaint as if fully set forth herein.

48. This is an action for a judgment declaring that the claims of the '446 and '319 patents are invalid and unenforceable, and not infringed, either literally or under the doctrine of equivalents, by the Fresenius NDA Product. Copies of the '446 and '319 patents are attached to Millennium's Complaint.

THE PARTIES

49. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173.

50. Plaintiff-Counterclaim Defendant Millennium Pharmaceuticals, Inc. ("Millennium") avers that it is a corporation organized and existing under the laws of Delaware, with its principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts.

JURISDICTION AND VENUE

51. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

52. This Court has subject matter jurisdiction over the Counterclaim under 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202.

53. Plaintiff-Counterclaim Defendant Millennium Pharmaceuticals, Inc. submitted to the personal jurisdiction of this Court by filing its Complaint in this action.

54. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b) and (c).

THE EXISTENCE OF AN ACTUAL CONTROVERSY

55. Plaintiff-Counterclaim Defendant Millennium's allegations of patent infringement against Fresenius Kabi USA, LLC in this action have created an actual controversy between Fresenius Kabi USA, LLC and Millennium regarding the validity, infringement, and enforceability of each claim of the '446 and '319 patents.

First Count (Non-infringement of the '446 patent)

56. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC repeats and incorporates by reference Paragraphs 47-55 of this Answer and Counterclaim as if fully set forth herein.

57. As part of the notice provided to Millennium concerning the filing of the Fresenius NDA, Fresenius Kabi USA, LLC also provided an Offer of Confidential Access ("OCA"). Under the OCA, Fresenius Kabi USA, LLC offered to allow Millennium to review portions of its NDA before this litigation was instituted to assess whether there was a good faith basis for filing this litigation.

58. The parties entered into a negotiated OCA on February 22, 2013.

59. On February 28, 2013, Fresenius Kabi USA, LLC provided a confidential copy of its NDA to counsel for Millennium to allow Millennium to assess whether to file a lawsuit and the basis for doing so. Millennium was aware of the formulation of the Fresenius NDA before it filed this lawsuit.

60. There is no reasonable basis for Millennium to assert infringement of the '446 patent.

61. Millennium was aware that there was no good faith basis to file this lawsuit at the time it was filed.

62. Fresenius Kabi USA, LLC's manufacture, use, offer for sale, sale or importation into the United States of the Fresenius NDA Product will not infringe any claim of the '446 patent, either literally or under the doctrine of equivalents.

Second Count (Non-infringement of the '319 patent)

63. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC repeats and incorporates by reference Paragraphs 47-62 of this Answer and Counterclaim as if fully set forth herein.

64. As part of the notice provided to Millennium concerning the filing of the Fresenius NDA, Fresenius Kabi USA, LLC also provided an Offer of Confidential Access ("OCA"). Under the OCA, Fresenius Kabi USA, LLC offered to allow Millennium to review portions of its NDA before this litigation was instituted to assess whether there was a good faith basis for filing this litigation.

65. The parties entered into a negotiated OCA on February 22, 2013.

66. On February 28, 2013, Fresenius Kabi USA, LLC provided a confidential copy of its NDA to counsel for Millennium to allow Millennium to assess whether to file a lawsuit and the basis for doing so. Millennium was aware of the formulation of the Fresenius NDA before it filed this lawsuit.

67. There is no reasonable basis for Millennium to assert infringement of the '319 patent.

68. Millennium was aware that there was no good faith basis to file this lawsuit at the time it was filed.

69. Fresenius Kabi USA, LLC's manufacture, use, offer for sale, sale or importation into the United States of the Fresenius NDA Product will not infringe any claim of the '319 patent, either literally or under the doctrine of equivalents.

Third Count (Invalidity of the '446 patent)

70. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC repeats and hereby incorporates by reference Paragraphs 47-69 of this Answer and Counterclaim as if fully set forth herein.

71. The claims of the '446 patent are invalid because they do not comply with one or more of the requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.* including, without limitation, those identified in 35 U.S.C. §§ 101-103, 112, 116, or for obviousness-type double patenting.

Fourth Count (Invalidity of the '319 patent)

72. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC repeats and hereby incorporates by reference Paragraphs 47-71 of this Answer and Counterclaim as if fully set forth herein.

73. The claims of the '319 patent are invalid because they do not comply with one or more of the requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.* including, without limitation, those identified in 35 U.S.C. §§ 101-103, 112, 116, or for obviousness-type double patenting.

Fifth Count (Exceptional case)

74. Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC repeats and hereby incorporates by reference Paragraphs 47-73 of this Answer and Counterclaim as if fully set forth herein.

75. This is an exceptional case, and Fresenius Kabi USA, LLC is entitled to an award of reasonable attorney fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius requests the Court to enter Judgment in its favor and against Millennium as follows:

1. Dismissing all of Millennium's claims with prejudice;

2. Adjudging that Fresenius has not and will not infringe any claim of the '446 or '319 patents;

3. Adjudging that the claims of the '446 and '319 patents are invalid;

4. Granting Fresenius judgment in its favor on Millennium's claims;

5. Denying Millennium's request for injunctive relief;

6. Declaring that Fresenius Kabi USA, LLC has not and will not infringe any claim of the '446 or '319 patents;

7. Declaring that the claims of the '446 and '319 patents are invalid;

8. Finding this to be an exceptional case under 35 U.S.C. § 285 and awarding Fresenius reasonable attorney fees and costs;

9. Awarding Fresenius such other and further relief as this Court may deem just, proper or equitable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*

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Dated: April 12, 2013
1102103 / 40167

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horiwtz, hereby certify that on April 12, 2013, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on April 12, 2013, the attached document was electronically mailed to the following person(s)

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