IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON, INC., and EAGLE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No.
FRESENIUS KABI USA, LLC, and MYLAN LABORATORIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon, Inc. ("Cephalon," and collectively with Teva Pharmaceuticals, "Teva"), and Eagle Pharmaceuticals, Inc. ("Eagle") (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Fresenius Kabi USA, LLC's ("Fresenius Kabi") submission of Abbreviated New Drug Application ("ANDA") No. 210410 and Mylan Laboratories Ltd.'s ("Mylan") submission of ANDA No. 210827 to the U.S. Food and Drug Administration ("FDA"). Both ANDAs seek approval to manufacture and sell generic versions of BENDEKA® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL)

("BENDEKA®"), prior to the expiration of U.S. Patent Nos. 10,010,533 (the "'533 patent") and 10,052,385 (the "'385 patent").

PARTIES

2. Plaintiff Teva Pharmaceuticals is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

3. Plaintiff Cephalon is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

4. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

5. Upon information and belief, Defendant Fresenius Kabi is a limited liability company organized and existing under the laws of Delaware, having its corporate offices and principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

6. Upon information and belief, Defendant Mylan is a company organized and existing under the laws of the Republic of India having its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad 500034, Republic of India.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Fresenius Kabi is incorporated in Delaware and therefore resides there for purposes of venue.

9. In addition, venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Mylan is a foreign company that may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction. As set forth *infra*, Mylan is subject to the Court's personal jurisdiction in this district.

10. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Fresenius Kabi.

11. This Court has personal jurisdiction over Fresenius Kabi because, upon information and belief, Fresenius Kabi is a corporation organized and existing under the laws of Delaware, has registered to do business in Delaware, and has appointed a registered agent in Delaware to accept service of process. Fresenius Kabi has thus consented to jurisdiction in Delaware.

12. In addition, this Court also has personal jurisdiction over Fresenius Kabi because, among other things, upon information and belief: (1) Fresenius Kabi filed ANDA No. 210410 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 210410 in the United States, including in Delaware; and (2) Fresenius Kabi will market, distribute, offer for sale, and/or sell the generic product described in ANDA No. 210410 in the United States, including in Delaware, upon approval of ANDA No. 210410 and will derive substantial revenue

from the use or consumption of the generic product described in ANDA No. 210410 in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). Upon information and belief, if ANDA No. 210410 is approved, the generic product described in ANDA No. 210410 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

13. The Court also has personal jurisdiction over Fresenius Kabi because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

14. Fresenius Kabi has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g.*, *Fresenius Kabi USA, LLC v. Sagent Pharm., Inc.*, C.A. No. 17-00011-LPS, D.I. 1 (D. Del. Jan. 4, 2017); *Fresenius Kabi USA, LLC v. B. Braun Med. Inc.*, C.A. No. 16-00250-RGA, D.I. 1 (D. Del. Apr. 11, 2016); *Fresenius Kabi USA, LLC v. Maia Pharm., Inc.*, C.A. No. 16-00237-GMS, D.I. 1 (D. Del. Apr. 7, 2016); *Fresenius Kabi USA, LLC v. Dr. Reddy's Labs., Inc.*, C.A. No. 16-00169-GMS, D.I. 1 (D. Del. Mar. 17, 2016); *Fresenius Kabi USA, LLC v. Mylan Labs. Ltd.*, C.A. No. 14-01438-RGA, D.I. 1 (D. Del. Nov. 26, 2014); *Fresenius Kabi USA, LLC v. Dr. Reddy's Labs., Ltd.*, C.A. No. 14-00160-RGA, D.I. 1 (D. Del. Feb. 6, 2014).

15. Fresenius Kabi has also previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in

such cases, including in a case between Plaintiffs and Fresenius Kabi regarding Fresenius Kabi's ANDA No. 210410. *See, e.g.*, *Teva Pharm. Int'l GmbH v. Fresenius Kabi USA, LLC*, C.A. No. 17-01201-CFC, D.I. 10 (D. Del. Sept. 15, 2017); *Onyx Therapeutics, Inc. v. Fresenius Kabi USA, LLC & Fresenius Kabi USA, Inc.*, C.A. No. 16-01012-LPS, D.I. 19 (D. Del. Jan. 6, 2017); *Shire Orphan Therapies LLC v. Fresenius Kabi USA, LLC*, C.A. No. 15-01102-GMS, D.I. 11 (D. Del. Jan. 13, 2016); *Cephalon, Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 15-01074-SLR, D.I. 8 (D. Del. Nov. 25, 2015); *Cephalon, Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 15-00536-LPS, D.I. 9 (D. Del. July 31, 2015); *Astellas Pharma Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 15-00080-LPS, D.I. 7 (D. Del. Feb. 13, 2015); *Cubist Pharm., Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 14-00914-GMS, D.I. 7 (D. Del. Aug. 1, 2014); *Celgene Corp. v. Fresenius Kabi USA, LLC*, C.A. No. 14-00571-RGA, D.I. 9 (D. Del. May 9, 2014).

16. For the above reasons, it would not be unfair or unreasonable for Fresenius Kabi to litigate this action in this District, and there is personal jurisdiction over Fresenius Kabi here.

17. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Mylan.

18. This Court has personal jurisdiction over Mylan because, upon information and belief, Mylan has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

19. In addition, this Court also has personal jurisdiction over Mylan because, among other things, upon information and belief: (1) Mylan filed ANDA No. 210827 for the

purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 210827 in the United States, including in Delaware; and (2) Mylan will market, distribute, offer for sale, and/or sell the generic product described in ANDA No. 210827 in the United States, including in Delaware, upon approval of ANDA No. 210827 and will derive substantial revenue from the use or consumption of the generic product described in ANDA No. 210827 in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). Upon information and belief, if ANDA No. 210827 is approved, the generic product described in ANDA No. 210827 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

20. The Court also has personal jurisdiction over Mylan because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

21. Mylan has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs or New Drug Applications ("NDA"). *See, e.g.*, *Cadence Pharm., Inc. v. Agila Specialties Pvt. Ltd.*, C.A. No. 14-01499-LPS (D. Del. June 19, 2015); *Cubist Pharm., Inc. v. Strides, Inc.*, C.A. No. 13-01679-GMS, D.I. 8 (D. Del. Nov. 13, 2013).

22. In addition, Mylan has purposefully availed itself of this forum by asserting counterclaims in prior cases arising out of the filing of its ANDAs. *See, e.g.*, *Javelin*

Pharm., Inc. v. Mylan Labs. Ltd., C.A. No. 16-00224-LPS, D.I. 15 (D. Del. June 13, 2016); *Fresenius Kabi USA, LLC v. Mylan Labs. Ltd.*, C.A. No. 15-00942-LPS, D.I. 28 (D. Del. June 3, 2016); *Pfizer, Inc. v. Mylan Inc.*, C.A. No. 15-00026-SLR-SRF, D.I. 150 (D. Del. May 17, 2016); *Millennium Pharm., Inc. v. Onco Therapies Ltd.*, C.A. No. 15-00040-GMS, D.I. 13 (D. Del. Apr. 27, 2015); *Cadence Pharm., Inc. v. Agila Specialties Pvt. Ltd.*, C.A. No. 13-01679-GMS, D.I. 23 (D. Del. June 19, 2015); *Cubist Pharm., Inc. v. Strides, Inc.*, C.A. No. 13-01679-GMS, D.I. 8 (D. Del. Nov. 13, 2013).

23. For the above reasons, it would not be unfair or unreasonable for Mylan to litigate this action in this District, and there is personal jurisdiction over Mylan here.

BACKGROUND

24. BENDEKA®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

25. Eagle is the holder of NDA No. 208194 for BENDEKA®, which has been approved by the FDA.

26. The ’533 patent, entitled “Formulations of Bendamustine” (Exhibit A hereto), was duly and legally issued on July 3, 2018. Eagle Pharmaceuticals, Inc. is the owner and assignee of the ’533 patent, subject to the exclusive license referenced herein. The ’533 patent has been listed in connection with BENDEKA® in the Orange Book.

27. The ’385 patent, entitled “Formulations of Bendamustine” (Exhibit B hereto), was duly and legally issued on August 21, 2018. Eagle Pharmaceuticals, Inc. is the

owner and assignee of the ’385 patent, subject to the exclusive license referenced herein. The ’385 patent has been listed in connection with BENDEKA® in the Orange Book.

28. On or around February 13, 2015, Cephalon executed an exclusive license (the “Eagle license”) to, *inter alia*, U.S. Patent No. 8,609,707, U.S. Patent Application No. 13/838,090 (which later issued as U.S. Patent No. 9,034,908), and all patent rights claiming priority to those patents or patent applications (which include the ’533 and ’385 patents), for the commercialization of Eagle’s bendamustine hydrochloride rapid infusion product, EP-3102, which became BENDEKA®. The Eagle license provides Cephalon the right to sue for infringement of the licensed patents in the event of, *inter alia*, the filing of an ANDA that makes reference to BENDEKA® and seeks approval before expiry of a licensed patent.

29. On or around October 14, 2015, Cephalon assigned its rights in the Eagle license to Teva Pharmaceuticals.

INFRINGEMENT BY FRESENIUS KABI

30. By letter dated August 6, 2018 (“Fresenius Kabi’s ’553 Notice Letter”), Fresenius Kabi notified Eagle that Fresenius Kabi had filed a Paragraph IV Certification with respect to the ’533 patent and that Fresenius Kabi was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi’s ANDA Product prior to the expiration of the ’533 patent. Upon information and belief, Fresenius Kabi submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’553 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Fresenius Kabi’s ANDA Product, or alternatively, that the ’533 patent is invalid.

31. By letter dated August 31, 2018 ("Fresenius Kabi's '385 Notice Letter"), Fresenius Kabi notified Eagle that Fresenius Kabi had filed a Paragraph IV Certification with respect to the '385 patent and that Fresenius Kabi was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi's ANDA Product prior to the expiration of the '385 patent. Upon information and belief, Fresenius Kabi submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '385 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Fresenius Kabi's ANDA Product, or alternatively, that the '385 patent is invalid. Upon information and belief, Fresenius's ANDA Product is a drug product that is a generic version of BENDEKA®, containing the same or equivalent ingredients in the same or equivalent amounts.

32. The purpose of Fresenius Kabi's submission of ANDA No. 210410 was to obtain approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi's ANDA Product prior to the expiration of the '533 and '385 patents.

33. In Fresenius Kabi's '553 and '385 Notice Letters, Fresenius Kabi stated that the active ingredient of Fresenius Kabi's ANDA Product is bendamustine hydrochloride.

34. In Fresenius Kabi's '553 and '385 Notice Letters, Fresenius Kabi stated that the proposed dosage strength of Fresenius Kabi's ANDA Product is 25 mg/mL.

35. Upon information and belief, Fresenius Kabi's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as BENDEKA®.

36. Upon information and belief, the proposed labeling for Fresenius Kabi's ANDA Product recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

37. Upon information and belief, the proposed labeling for Fresenius Kabi's ANDA Product recommends, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

38. Upon information and belief, the proposed labeling for Fresenius Kabi's ANDA Product recommends, instructs, and/or promotes the administration of Fresenius Kabi's ANDA Product in a volume of about 50 mL or less over a 10-minute period.

INFRINGEMENT BY MYLAN

39. By letter dated August 30, 2018 ("Mylan's '553 Notice Letter"), Mylan notified Eagle and Teva that Mylan had filed a Paragraph IV Certification with respect to the '533 patent and that Mylan was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '533 patent. Upon information and belief, Mylan submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '553 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Mylan's ANDA Product, or alternatively, that the '533 patent is invalid.

40. By letter dated September 28, 2018 ("Mylan's '385 Notice Letter"), Mylan notified Eagle and Teva that Mylan had filed a Paragraph IV Certification with respect to the '385 patent and that Mylan was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '385 patent. Upon information and belief, Mylan submitted a Paragraph IV

Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '385 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Mylan's ANDA Product, or alternatively, that the '385 patent is invalid. Upon information and belief, Mylan's ANDA Product is a drug product that is a generic version of BENDEKA®, containing the same or equivalent ingredients in the same or equivalent amounts.

41. The purpose of Mylan's submission of ANDA No. 210827 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '553 and '385 patents.

42. In Mylan's '553 and '385 Notice Letters, Mylan stated that the active ingredient of Mylan's ANDA Product is bendamustine hydrochloride.

43. In Mylan's '553 and '385 Notice Letters, Mylan stated that the proposed dosage strength of Mylan's ANDA Product is 25 mg/mL.

44. Upon information and belief, Mylan's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as BENDEKA®.

45. Upon information and belief, the proposed labeling for Mylan's ANDA Product recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

46. Upon information and belief, the proposed labeling for Mylan's ANDA Product recommends, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

47. Upon information and belief, the proposed labeling for Mylan's ANDA Product recommends, instructs, and/or promotes the administration of Mylan's ANDA Product in a volume of about 50 mL or less over a 10-minute period.

COUNT I – INFRINGEMENT BY FRESENIUS KABI OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)

48. Plaintiffs incorporate each of the preceding paragraphs 1–47 as if fully set forth herein.

49. Fresenius Kabi's submission of ANDA No. 210410 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi's ANDA Product prior to the expiration of the '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A).

50. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi's ANDA Product would infringe one or more claims of the '533 patent, either literally or under the doctrine of equivalents.

51. Upon information and belief, Fresenius Kabi will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210410.

52. Upon information and belief, the use of Fresenius Kabi's ANDA Product in accordance with and as directed by Fresenius Kabi's proposed labeling for that product would infringe one or more claims of the '533 patent.

53. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '533 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

54. Upon information and belief, Fresenius Kabi knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi plans and intends to, and will, contribute to infringement of the ’533 patent after approval of ANDA No. 210410.

55. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the ’533 patent, active inducement of infringement of the ’533 patent, and contribution to the infringement by others of the ’533 patent.

56. Upon information and belief, Fresenius Kabi has acted with full knowledge of the ’533 patent and without a reasonable basis for believing that it would not be liable for infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent.

57. Unless Fresenius Kabi is enjoined from infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – INFRINGEMENT BY FRESENIUS KABI OF U.S. PATENT NO. 10,052,385 UNDER 35 U.S.C. § 271(e)(2)

58. Plaintiffs incorporate each of the preceding paragraphs 1–57 as if fully set forth herein.

59. Fresenius Kabi’s submission of ANDA No. 210410 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi’s ANDA Product prior to the expiration of the ’385 patent was an act of infringement of the ’385 patent under 35 U.S.C. § 271(e)(2)(A).

60. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi's ANDA Product would infringe one or more claims of the '385 patent, either literally or under the doctrine of equivalents.

61. Upon information and belief, Fresenius Kabi will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210410.

62. Upon information and belief, the use of Fresenius Kabi's ANDA Product in accordance with and as directed by Fresenius Kabi's proposed labeling for that product would infringe one or more claims of the '385 patent.

63. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '385 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

64. Upon information and belief, Fresenius Kabi knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '385 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi plans and intends to, and will, contribute to infringement of the '385 patent after approval of ANDA No. 210410.

65. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '385 patent, active inducement of infringement of the '385 patent, and contribution to the infringement by others of the '385 patent.

66. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '385 patent and without a reasonable basis for believing that it would not be

liable for infringing the ’385 patent, actively inducing infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent.

67. Unless Fresenius Kabi is enjoined from infringing the ’385 patent, actively inducing infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT BY FRESENIUS KABI OF U.S. PATENT NO. 10,010,533

68. Plaintiffs incorporate each of the preceding paragraphs 1–67 as if fully set forth herein.

69. Fresenius Kabi has knowledge of the ’533 patent.

70. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi’s ANDA Product would infringe one or more claims of the ’533 patent, either literally or under the doctrine of equivalents.

71. Upon information and belief, Fresenius Kabi will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210410.

72. Upon information and belief, the use of Fresenius Kabi’s ANDA Product in accordance with and as directed by Fresenius Kabi’s proposed labeling for that product would infringe one or more claims of the ’533 patent.

73. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the ’533 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

74. Upon information and belief, Fresenius Kabi knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’533

patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi plans and intends to, and will, contribute to infringement of the ’533 patent after approval of ANDA No. 210410.

75. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the ’533 patent, active inducement of infringement of the ’533 patent, and contribution to the infringement by others of the ’533 patent.

76. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent.

77. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Fresenius Kabi regarding whether Fresenius Kabi’s manufacture, use, sale, offer for sale, or importation into the United States of Fresenius Kabi’s ANDA Product with its proposed labeling according to ANDA No. 210410 will infringe one or more claims of the ’533 patent and whether one or more claims of the ’533 patent are valid.

78. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Fresenius Kabi’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’533 patent and that the claims of the ’533 patent are valid.

79. Fresenius Kabi should be enjoined from infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY FRESENIUS KABI OF U.S. PATENT NO. 10,052,385

80. Plaintiffs incorporate each of the preceding paragraphs 1–79 as if fully set forth herein.

81. Fresenius Kabi has knowledge of the ’385 patent.

82. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi’s ANDA Product would infringe one or more claims of the ’385 patent, either literally or under the doctrine of equivalents.

83. Upon information and belief, Fresenius Kabi will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius Kabi’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210410.

84. Upon information and belief, the use of Fresenius Kabi’s ANDA Product in accordance with and as directed by Fresenius Kabi’s proposed labeling for that product would infringe one or more claims of the ’385 patent.

85. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the ’385 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

86. Upon information and belief, Fresenius Kabi knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius Kabi plans and intends to, and will, contribute to infringement of the ’385 patent after approval of ANDA No. 210410.

87. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the ’533 patent, active inducement of infringement of the ’385 patent, and contribution to the infringement by others of the ’385 patent.

88. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the ’385 patent, actively inducing infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent.

89. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Fresenius Kabi regarding whether Fresenius Kabi’s manufacture, use, sale, offer for sale, or importation into the United States of Fresenius Kabi’s ANDA Product with its proposed labeling according to ANDA No. 210410 will infringe one or more claims of the ’385 patent and whether one or more claims of the ’385 patent are valid.

90. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Fresenius Kabi’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’385 patent and that the claims of the ’385 patent are valid.

91. Fresenius Kabi should be enjoined from infringing the ’385 patent, actively inducing infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – INFRINGEMENT BY MYLAN
OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)

92. Plaintiffs incorporate each of the preceding paragraphs 1–91 as if fully set forth herein.

93. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A).

94. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '533 patent, either literally or under the doctrine of equivalents.

95. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

96. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '533 patent.

97. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '533 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

98. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '533 patent after approval of ANDA No. 210827.

99. The foregoing actions by Mylan constitute and/or will constitute infringement of the ’533 patent, active inducement of infringement of the ’533 patent, and contribution to the infringement by others of the ’533 patent.

100. Upon information and belief, Mylan has acted with full knowledge of the ’533 patent and without a reasonable basis for believing that it would not be liable for infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent.

101. Unless Mylan is enjoined from infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – INFRINGEMENT BY MYLAN
OF U.S. PATENT NO. 10,052,385 UNDER 35 U.S.C. § 271(e)(2)

102. Plaintiffs incorporate each of the preceding paragraphs 1–101 as if fully set forth herein.

103. Mylan’s submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan’s ANDA Product prior to the expiration of the ’385 patent was an act of infringement of the ’385 patent under 35 U.S.C. § 271(e)(2)(A).

104. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Product would infringe one or more claims of the ’385 patent, either literally or under the doctrine of equivalents.

105. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

106. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '385 patent.

107. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '385 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

108. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '385 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '385 patent after approval of ANDA No. 210827.

109. The foregoing actions by Mylan constitute and/or will constitute infringement of the '385 patent, active inducement of infringement of the '385 patent, and contribution to the infringement by others of the '385 patent.

110. Upon information and belief, Mylan has acted with full knowledge of the '385 patent and without a reasonable basis for believing that it would not be liable for infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent.

111. Unless Mylan is enjoined from infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VII – DECLARATORY JUDGMENT OF INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 10,010,533

112. Plaintiffs incorporate each of the preceding paragraphs 1–111 as if fully set forth herein.

113. Mylan has knowledge of the ’533 patent.

114. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Product would infringe one or more claims of the ’533 patent, either literally or under the doctrine of equivalents.

115. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

116. Upon information and belief, the use of Mylan’s ANDA Product in accordance with and as directed by Mylan’s proposed labeling for that product would infringe one or more claims of the ’533 patent.

117. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the ’533 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

118. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the ’533 patent after approval of ANDA No. 210827.

119. The foregoing actions by Mylan constitute and/or will constitute infringement of the ’533 patent, active inducement of infringement of the ’533 patent, and contribution to the infringement by others of the ’533 patent.

120. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent.

121. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan’s manufacture, use, sale, offer for sale, or importation into the United States of Mylan’s ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the ’533 patent and whether one or more claims of the ’533 patent are valid.

122. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’533 patent and that the claims of the ’533 patent are valid.

123. Mylan should be enjoined from infringing the ’533 patent, actively inducing infringement of the ’533 patent, and contributing to the infringement by others of the ’533 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY MYLAN OF U.S. PATENT NO. 10,052,385

124. Plaintiffs incorporate each of the preceding paragraphs 1–123 as if fully set forth herein.

125. Mylan has knowledge of the ’385 patent.

126. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '385 patent, either literally or under the doctrine of equivalents.

127. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

128. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '385 patent.

129. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '385 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

130. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '385 patent after approval of ANDA No. 210827.

131. The foregoing actions by Mylan constitute and/or will constitute infringement of the '533 patent, active inducement of infringement of the '385 patent, and contribution to the infringement by others of the '385 patent.

132. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '385 patent, actively inducing

infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent.

133. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan’s manufacture, use, sale, offer for sale, or importation into the United States of Mylan’s ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the ’385 patent and whether one or more claims of the ’385 patent are valid.

134. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’385 patent and that the claims of the ’385 patent are valid.

135. Mylan should be enjoined from infringing the ’385 patent, actively inducing infringement of the ’385 patent, and contributing to the infringement by others of the ’385 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Fresenius Kabi has infringed, will infringe, and will induce and contribute to infringement of the ’533 and ’385 patents (the “Patents-in-Suit”).

(b) A judgment that Mylan has infringed, will infringe, and will induce and contribute to infringement of the Patents-in-Suit.

(c) A judgment that the Patents-in-Suit are valid and enforceable;

(d) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Fresenius Kabi to make, use, offer for sale, sell,

market, distribute, or import Fresenius Kabi's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Fresenius Kabi, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Fresenius Kabi's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Mylan, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-

Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Fresenius Kabi's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(i) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(j) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Fresenius Kabi engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Fresenius Kabi's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(k) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Mylan engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

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

(m) An award of Plaintiffs' costs and expenses in this action; and

(n) Such further and other relief as this Court may deem just and proper.

/s/ Nathan R. Hoeschen

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