

**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,)	
)	
Defendant.)	
_____)	

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 defendant’s submission of Abbreviated New Drug Application (“ANDA”) No. 210410 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of BENDEKA[®] (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL) (“BENDEKA[®]”) prior to the expiration of U.S. Patent Nos. 8,791,270 (“the ’270 patent”); 8,609,707 (“the ’707 patent”); 9,265,831 (“the ’831 patent”); 9,572,796 (“the ’796 patent”); 9,572,797 (“the ’797 patent”); 9,034,908 (“the ’908

patent”); 9,144,568 (“the ’568 patent”); 9,572,887 (“the ’887 patent”); 9,597,397 (“the ’397 patent”); 9,597,398 (“the ’398 patent”); 9,597,399 (“the ’399 patent”); 9,000,021 (“the ’021 patent”); and 9,579,384 (“the ’384 patent”) (together, “the Orange Book patents”).

PARTIES

2. Plaintiff Teva Pharmaceuticals International GmbH 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, Inc. 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 Pharmaceuticals, Inc. 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. On information and belief, defendant Fresenius Kabi USA, LLC (“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.

JURISDICTION AND VENUE

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

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Fresenius Kabi is organized and existing under the laws of Delaware and therefore resides there for purposes of venue.

8. 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.

9. This Court has personal jurisdiction over Fresenius Kabi because, on information and belief, Fresenius Kabi is a limited liability company organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Fresenius Kabi has thus consented to jurisdiction in Delaware.

10. In addition, this Court also has personal jurisdiction over Fresenius Kabi because, among other things, on information and belief: (1) Fresenius Kabi has filed an ANDA 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 the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On 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.

11. 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.

12. 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 file 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).

13. 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. *See, e.g., 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).

14. 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.

BACKGROUND

15. 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.

16. Eagle is the holder of New Drug Application No. 208194 for BENDEKA[®], which has been approved by the FDA.

17. The '270 patent, entitled "Bendamustine Pharmaceutical Compositions" (Exhibit A hereto), was duly and legally issued on July 29, 2014. Cephalon, Inc. is the owner and assignee of the '270 patent. The '270 patent has been listed in connection with BENDEKA[®] in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '707 patent, entitled "Formulations of Bendamustine" (Exhibit B hereto), was duly and legally issued on December 17, 2013. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '707 patent, subject to the exclusive license referenced herein. The '707 patent has been listed in connection with BENDEKA[®] in the Orange Book.

19. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit C hereto), was duly and legally issued on February 23, 2016. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '831 patent, subject to the exclusive license referenced herein. The '831 patent has been listed in connection with BENDEKA® in the Orange Book.

20. The '796 patent, entitled "Formulations of Bendamustine" (Exhibit D hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '796 patent, subject to the exclusive license referenced herein. The '796 patent has been listed in connection with BENDEKA® in the Orange Book.

21. The '797 patent, entitled "Formulations of Bendamustine" (Exhibit E hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '797 patent, subject to the exclusive license referenced herein. The '797 patent has been listed in connection with BENDEKA® in the Orange Book.

22. The '908 patent, entitled "Formulations of Bendamustine" (Exhibit F hereto), was duly and legally issued on May 19, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '908 patent, subject to the exclusive license referenced herein. The '908 patent has been listed in connection with BENDEKA® in the Orange Book.

23. The '568 patent, entitled "Formulations of Bendamustine" (Exhibit G hereto), was duly and legally issued on September 29, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '568 patent, subject to the exclusive license referenced herein. The '568 patent has been listed in connection with BENDEKA® in the Orange Book.

24. The '887 patent, entitled "Formulations of Bendamustine" (Exhibit H hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the

owner and assignee of the '887 patent, subject to the exclusive license referenced herein. The '887 patent has been listed in connection with BENDEKA® in the Orange Book.

25. The '397 patent, entitled "Formulations of Bendamustine" (Exhibit I hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '397 patent, subject to the exclusive license referenced herein. The '397 patent has been listed in connection with BENDEKA® in the Orange Book.

26. The '398 patent, entitled "Formulations of Bendamustine" (Exhibit J hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '398 patent, subject to the exclusive license referenced herein. The '398 patent has been listed in connection with BENDEKA® in the Orange Book.

27. The '399 patent, entitled "Formulations of Bendamustine" (Exhibit K hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '399 patent, subject to the exclusive license referenced herein. The '399 patent has been listed in connection with BENDEKA® in the Orange Book.

28. The '021 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit L hereto), was duly and legally issued on April 7, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '021 patent, subject to the exclusive license referenced herein. The '021 patent has been listed in connection with BENDEKA® in the Orange Book.

29. The '384 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit M hereto), was duly and legally issued on February 28, 2017. Eagle Pharmaceuticals, Inc. is the owner and

assignee of the '384 patent, subject to the exclusive license referenced herein. The '384 patent has been listed in connection with BENDEKA[®] in the Orange Book.

30. On or around February 13, 2015, Cephalon executed an exclusive license (“the Eagle license”) to, *inter alia*, the '707 patent, patent application no. 14/031,879 (which later issued as the '831 patent), patent application no. 13/838,090 (which later issued as the '908 patent), and patent application no. 13/838,267 (which later issued as the '021 patent), and all patent rights claiming priority to those patents or patent applications (which include the '796, '797, '568, '887, '397, '398, '399, and '384 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.

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

INFRINGEMENT BY FRESENIUS KABI

32. By letter dated July 14, 2017 (the “Notice Letter”), Fresenius Kabi notified Cephalon and Eagle pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that Fresenius Kabi had submitted to the FDA ANDA No. 210410, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic Bendamustine Hydrochloride Injection, 25 mg/mL in a 5 mL glass vial (“Fresenius Kabi's ANDA Product”) prior to the expiration of the Orange Book patents. Upon information and belief, Fresenius Kabi'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.

33. The purpose of Fresenius Kabi's submission of ANDA No. 210410 was to obtain approval under the 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 Orange Book patents.

34. In the Notice Letter, Fresenius Kabi also notified Cephalon and Eagle that, as part of its ANDA No. 210410, Fresenius Kabi had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification"), with respect to the Orange Book patents. Upon information and belief, Fresenius Kabi submitted ANDA No. 210410 to the FDA containing a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the Orange Book patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Fresenius Kabi's ANDA Product, or alternatively, that these patents are invalid.

35. In the Notice Letter, Fresenius Kabi stated that the active ingredient of Fresenius Kabi's ANDA Product is bendamustine hydrochloride.

36. In the Notice Letter, Fresenius Kabi stated that the proposed dosage strength of Fresenius Kabi's ANDA Product is 25 mg/mL.

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

38. 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.

39. Upon information and belief, the proposed labeling for Fresenius Kabi's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m² to patients with chronic lymphocytic leukemia.

40. 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.

41. Upon information and belief, the proposed labeling for Fresenius Kabi's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m² to patients with indolent B-cell non-Hodgkin lymphoma.

42. 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.

43. In an exchange of correspondence, counsel for Fresenius Kabi and counsel for Teva discussed the terms of Teva's Request for Confidential Access. The parties did not agree on terms under which Teva could review, *inter alia*, Fresenius Kabi's ANDA and certain portions of the Drug Master File referred to therein, and Fresenius Kabi refused to produce other internal documents and data relevant to infringement.

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

**COUNT I – INFRINGEMENT OF U.S. PATENT
NO. 8,791,270 UNDER 35 U.S.C. § 271(e)(2)**

45. Plaintiffs incorporate each of the preceding paragraphs 1–44 as if fully set forth herein.

46. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

47. 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 '270 patent was an act of infringement of the '270 patent under 35 U.S.C. § 271(e)(2)(A).

48. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '270 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

49. 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 '270 patent, either literally or under the doctrine of equivalents.

50. 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.

51. 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 '270 patent.

52. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

53. 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 '270

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 '270 patent after approval of ANDA No. 210410.

54. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '270 patent, active inducement of infringement of the '270 patent, and contribution to the infringement by others of the '270 patent.

55. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '270 patent and without a reasonable basis for believing that it would not be liable for infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent.

56. Unless Fresenius Kabi is enjoined from infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – INFRINGEMENT OF U.S. PATENT
NO. 8,609,707 UNDER 35 U.S.C. § 271(e)(2)**

57. Plaintiffs incorporate each of the preceding paragraphs 1–56 as if fully set forth herein.

58. 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 '707 patent was an act of infringement of the '707 patent under 35 U.S.C. § 271(e)(2)(A).

59. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '707 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

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 '707 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 with its proposed labeling 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 '707 patent.

63. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '707 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 '707 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 '707 patent after approval of ANDA No. 210410.

65. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

66. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '707 patent and without a reasonable basis for believing that it would not be

liable for infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

67. Unless Fresenius Kabi is enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III – INFRINGEMENT OF U.S. PATENT
NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)**

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

69. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

70. 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 '831 patent was an act of infringement of the '831 patent under 35 U.S.C. § 271(e)(2)(A).

71. 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 '831 patent, either literally or under the doctrine of equivalents.

72. 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.

73. 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 '831 patent.

74. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '831 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

75. 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 '831 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 '831 patent after approval of ANDA No. 210410.

76. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

77. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '831 patent and without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

78. Unless Fresenius Kabi is enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – INFRINGEMENT OF U.S. PATENT
NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)**

79. Plaintiffs incorporate each of the preceding paragraphs 1–78 as if fully set forth herein.

80. 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 '796 patent was an act of infringement of the '796 patent under 35 U.S.C. § 271(e)(2)(A).

81. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '796 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

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 '796 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 immediately and imminently 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 '796 patent.

85. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '796 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 '796 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 '796 patent after approval of ANDA No. 210410.

87. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

88. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '796 patent and without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.

89. Unless Fresenius Kabi is enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT V – INFRINGEMENT OF U.S. PATENT
NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)**

90. Plaintiffs incorporate each of the preceding paragraphs 1–89 as if fully set forth herein.

91. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

92. 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 '797 patent was an act of infringement of the '797 patent under 35 U.S.C. § 271(e)(2)(A).

93. 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 '797 patent, either literally or under the doctrine of equivalents.

94. 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.

95. 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 '797 patent.

96. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

97. 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 '797 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 '797 patent after approval of ANDA No. 210410.

98. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

99. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be

liable for infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

100. Unless Fresenius Kabi is enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – INFRINGEMENT OF U.S. PATENT
NO. 9,034,908 UNDER 35 U.S.C. § 271(e)(2)**

101. Plaintiffs incorporate each of the preceding paragraphs 1–100 as if fully set forth herein.

102. 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 '908 patent was an act of infringement of the '908 patent under 35 U.S.C. § 271(e)(2)(A).

103. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '908 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

104. 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 '908 patent, either literally or under the doctrine of equivalents.

105. 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.

106. 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 '908 patent.

107. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '908 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

108. 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 '908 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 '908 patent after approval of ANDA No. 210410.

109. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

110. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '908 patent and without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

111. Unless Fresenius Kabi is enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VII – INFRINGEMENT OF U.S. PATENT
NO. 9,144,568 UNDER 35 U.S.C. § 271(e)(2)**

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

113. 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 '568 patent was an act of infringement of the '568 patent under 35 U.S.C. § 271(e)(2)(A).

114. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '568 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

115. 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 '568 patent, either literally or under the doctrine of equivalents.

116. 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.

117. 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 '568 patent.

118. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '568 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

119. 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 '568

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 '568 patent after approval of ANDA No. 210410.

120. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

121. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '568 patent and without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

122. Unless Fresenius Kabi is enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VIII – INFRINGEMENT OF U.S. PATENT
NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)**

123. Plaintiffs incorporate each of the preceding paragraphs 1–122 as if fully set forth herein.

124. 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 '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

125. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

126. 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 '887 patent, either literally or under the doctrine of equivalents.

127. 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.

128. 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 '887 patent.

129. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

130. 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 '887 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 '887 patent after approval of ANDA No. 210410.

131. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

132. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '887 patent and without a reasonable basis for believing that it would not be

liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

133. Unless Fresenius Kabi is enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IX – INFRINGEMENT OF U.S. PATENT
NO. 9,597,397 UNDER 35 U.S.C. § 271(e)(2)**

134. Plaintiffs incorporate each of the preceding paragraphs 1–133 as if fully set forth herein.

135. 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 '397 patent was an act of infringement of the '397 patent under 35 U.S.C. § 271(e)(2)(A).

136. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '397 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

137. 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 '397 patent, either literally or under the doctrine of equivalents.

138. 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.

139. 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 '397 patent.

140. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '397 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

141. 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 '397 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 '397 patent after approval of ANDA No. 210410.

142. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

143. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '397 patent and without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

144. Unless Fresenius Kabi is enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT X – INFRINGEMENT OF U.S. PATENT
NO. 9,597,398 UNDER 35 U.S.C. § 271(e)(2)**

145. Plaintiffs incorporate each of the preceding paragraphs 1–144 as if fully set forth herein.

146. 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 '398 patent was an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

147. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '398 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

148. 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 '398 patent, either literally or under the doctrine of equivalents.

149. 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.

150. 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 '398 patent.

151. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

152. 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 '398

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 '398 patent after approval of ANDA No. 210410.

153. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

154. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '398 patent and without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

155. Unless Fresenius Kabi is enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XI – INFRINGEMENT OF U.S. PATENT
NO. 9,597,399 UNDER 35 U.S.C. § 271(e)(2)**

156. Plaintiffs incorporate each of the preceding paragraphs 1–155 as if fully set forth herein.

157. 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 '399 patent was an act of infringement of the '399 patent under 35 U.S.C. § 271(e)(2)(A).

158. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '399 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

159. 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 '399 patent, either literally or under the doctrine of equivalents.

160. 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.

161. 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 '399 patent.

162. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '399 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

163. 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 '399 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 '399 patent after approval of ANDA No. 210410.

164. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

165. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '399 patent and without a reasonable basis for believing that it would not be

liable for infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

166. Unless Fresenius Kabi is enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XII – INFRINGEMENT OF U.S. PATENT
NO. 9,000,021 UNDER 35 U.S.C. § 271(e)(2)**

167. Plaintiffs incorporate each of the preceding paragraphs 1–166 as if fully set forth herein.

168. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

169. 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 '021 patent was an act of infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

170. 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 '021 patent, either literally or under the doctrine of equivalents.

171. 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.

172. 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 '021 patent.

173. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

174. 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 '021 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 '021 patent after approval of ANDA No. 210410.

175. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

176. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '021 patent and without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

177. Unless Fresenius Kabi is enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIII – INFRINGEMENT OF U.S. PATENT
NO. 9,579,384 UNDER 35 U.S.C. § 271(e)(2)**

178. Plaintiffs incorporate each of the preceding paragraphs 1–177 as if fully set forth herein.

179. 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 '384 patent was an act of infringement of the '384 patent under 35 U.S.C. § 271(e)(2)(A).

180. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '384 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

181. 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 '384 patent, either literally or under the doctrine of equivalents.

182. 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.

183. 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 '384 patent.

184. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '384 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

185. 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 '384

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 '384 patent after approval of ANDA No. 210410.

186. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

187. Upon information and belief, Fresenius Kabi has acted with full knowledge of the '384 patent and without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

188. Unless Fresenius Kabi is enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIV – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,791,270**

189. Plaintiffs incorporate each of the preceding paragraphs 1–188 as if fully set forth herein.

190. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

191. Fresenius Kabi has knowledge of the '270 patent.

192. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '270 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

193. 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 '270 patent, either literally or under the doctrine of equivalents.

194. 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.

195. 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 '270 patent.

196. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

197. 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 '270 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 '270 patent after approval of ANDA No. 210410.

198. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '270 patent, active inducement of infringement of the '270 patent, and contribution to the infringement by others of the '270 patent.

199. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '270 patent, actively

inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent.

200. 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 '270 patent and whether one or more claims of the '270 patent are valid.

201. 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 '270 patent and that the claims of the '270 patent are valid.

202. Fresenius Kabi should be enjoined from infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XV – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,609,707**

203. Plaintiffs incorporate each of the preceding paragraphs 1–202 as if fully set forth herein.

204. Fresenius Kabi has knowledge of the '707 patent.

205. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '707 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

206. 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 '707 patent, either literally or under the doctrine of equivalents.

207. 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.

208. 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 '707 patent.

209. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '707 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

210. 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 '707 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 '707 patent after approval of ANDA No. 210410.

211. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

212. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '707 patent, actively

inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

213. 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 '707 patent and whether one or more claims of the '707 patent are valid.

214. 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 '707 patent and that the claims of the '707 patent are valid.

215. Fresenius Kabi should be enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVI – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,265,831**

216. Plaintiffs incorporate each of the preceding paragraphs 1–215 as if fully set forth herein.

217. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

218. Fresenius Kabi has knowledge of the '831 patent.

219. 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 '831 patent, either literally or under the doctrine of equivalents.

220. 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.

221. 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 '831 patent.

222. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '831 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

223. 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 '831 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 '831 patent after approval of ANDA No. 210410.

224. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

225. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively

inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

226. 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 '831 patent and whether one or more claims of the '831 patent are valid.

227. 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 '831 patent and that the claims of the '831 patent are valid.

228. Fresenius Kabi should be enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVII – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,572,796**

229. Plaintiffs incorporate each of the preceding paragraphs 1–228 as if fully set forth herein.

230. Fresenius Kabi has knowledge of the '796 patent.

231. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '796 patent, including claim 1, cover Fresenius Kabi's ANDA Product.

232. 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 '796 patent, either literally or under the doctrine of equivalents.

233. 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.

234. 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 '796 patent.

235. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

236. 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 '796 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 '796 patent after approval of ANDA No. 210410.

237. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

238. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively

inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.

239. 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 '796 patent and whether one or more claims of the '796 patent are valid.

240. 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 '796 patent and that the claims of the '796 patent are valid.

241. Fresenius Kabi should be enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVIII – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,572,797**

242. Plaintiffs incorporate each of the preceding paragraphs 1–241 as if fully set forth herein.

243. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

244. Fresenius Kabi has knowledge of the '797 patent.

245. 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 '797 patent, either literally or under the doctrine of equivalents.

246. 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.

247. 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 '797 patent.

248. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

249. 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 '797 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 '797 patent after approval of ANDA No. 210410.

250. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

251. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '797 patent, actively

inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

252. 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 '797 patent and whether one or more claims of the '797 patent are valid.

253. 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 '797 patent and that the claims of the '797 patent are valid.

254. Fresenius Kabi should be enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIX – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,034,908**

255. Plaintiffs incorporate each of the preceding paragraphs 1–254 as if fully set forth herein.

256. Fresenius Kabi has knowledge of the '908 patent.

257. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '908 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

258. 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 '908 patent, either literally or under the doctrine of equivalents.

259. 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.

260. 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 '908 patent.

261. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '908 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

262. 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 '908 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 '908 patent after approval of ANDA No. 210410.

263. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

264. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively

inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

265. 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 '908 patent and whether one or more claims of the '908 patent are valid.

266. 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 '908 patent and that the claims of the '908 patent are valid.

267. Fresenius Kabi should be enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XX – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,144,568**

268. Plaintiffs incorporate each of the preceding paragraphs 1–267 as if fully set forth herein.

269. Fresenius Kabi has knowledge of the '568 patent.

270. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '568 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

271. 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 '568 patent, either literally or under the doctrine of equivalents.

272. 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.

273. 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 '568 patent.

274. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '568 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

275. 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 '568 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 '568 patent after approval of ANDA No. 210410.

276. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

277. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively

inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

278. 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 '568 patent and whether one or more claims of the '568 patent are valid.

279. 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 '568 patent and that the claims of the '568 patent are valid.

280. Fresenius Kabi should be enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXI – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,572,887**

281. Plaintiffs incorporate each of the preceding paragraphs 1–280 as if fully set forth herein.

282. Fresenius Kabi has knowledge of the '887 patent.

283. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

284. 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 '887 patent, either literally or under the doctrine of equivalents.

285. 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.

286. 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 '887 patent.

287. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

288. 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 '887 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 '887 patent after approval of ANDA No. 210410.

289. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

290. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively

inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

291. 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 '887 patent and whether one or more claims of the '887 patent are valid.

292. 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 '887 patent and that the claims of the '887 patent are valid.

293. Fresenius Kabi should be enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXII – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,597,397**

294. Plaintiffs incorporate each of the preceding paragraphs 1–293 as if fully set forth herein.

295. Fresenius Kabi has knowledge of the '397 patent.

296. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '397 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

297. 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 '397 patent, either literally or under the doctrine of equivalents.

298. 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.

299. 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 '397 patent.

300. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '397 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

301. 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 '397 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 '397 patent after approval of ANDA No. 210410.

302. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

303. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively

inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

304. 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 '397 patent and whether one or more claims of the '397 patent are valid.

305. 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 '397 patent and that the claims of the '397 patent are valid.

306. Fresenius Kabi should be enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXIII – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,597,398**

307. Plaintiffs incorporate each of the preceding paragraphs 1–306 as if fully set forth herein.

308. Fresenius Kabi has knowledge of the '398 patent.

309. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '398 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

310. 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 '398 patent, either literally or under the doctrine of equivalents.

311. 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.

312. 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 '398 patent.

313. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

314. 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 '398 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 '398 patent after approval of ANDA No. 210410.

315. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

316. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively

inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

317. 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 '398 patent and whether one or more claims of the '398 patent are valid.

318. 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 '398 patent and that the claims of the '398 patent are valid.

319. Fresenius Kabi should be enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXIV – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,597,399**

320. Plaintiffs incorporate each of the preceding paragraphs 1–319 as if fully set forth herein.

321. Fresenius Kabi has knowledge of the '399 patent.

322. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '399 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

323. 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 '399 patent, either literally or under the doctrine of equivalents.

324. 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.

325. 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 '399 patent.

326. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '399 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

327. 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 '399 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 '399 patent after approval of ANDA No. 210410.

328. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

329. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '399 patent, actively

inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

330. 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 '399 patent and whether one or more claims of the '399 patent are valid.

331. 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 '399 patent and that the claims of the '399 patent are valid.

332. Fresenius Kabi should be enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXV – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,000,021**

333. Plaintiffs incorporate each of the preceding paragraphs 1–332 as if fully set forth herein.

334. Notwithstanding Teva's Request for Confidential Access, Fresenius Kabi has not provided Teva with Fresenius Kabi's ANDA and other materials relevant to infringement.

335. Fresenius Kabi has knowledge of the '021 patent.

336. 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 '021 patent, either literally or under the doctrine of equivalents.

337. 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.

338. 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 '021 patent.

339. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

340. 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 '021 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 '021 patent after approval of ANDA No. 210410.

341. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

342. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively

inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

343. 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 '021 patent and whether one or more claims of the '021 patent are valid.

344. 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 '021 patent and that the claims of the '021 patent are valid.

345. Fresenius Kabi should be enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXVI – DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,579,384**

346. Plaintiffs incorporate each of the preceding paragraphs 1–345 as if fully set forth herein.

347. Fresenius Kabi has knowledge of the '384 patent.

348. In the Notice Letter, Fresenius Kabi did not contest that at least some of the claims of the '384 patent, including claim 1, cover the use of Fresenius Kabi's ANDA Product as directed by Fresenius Kabi's proposed labeling.

349. 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 '384 patent, either literally or under the doctrine of equivalents.

350. 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.

351. 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 '384 patent.

352. Upon information and belief, Fresenius Kabi plans and intends to, and will, actively induce infringement of the '384 patent when ANDA No. 210410 is approved, and plans and intends to, and will, do so after approval.

353. 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 '384 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 '384 patent after approval of ANDA No. 210410.

354. The foregoing actions by Fresenius Kabi constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

355. Upon information and belief, Fresenius Kabi has acted without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively

inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

356. 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 '384 patent and whether one or more claims of the '384 patent are valid.

357. 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 '384 patent and that the claims of the '384 patent are valid.

358. Fresenius Kabi should be enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 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 '270 patent, the '707 patent, the '831 patent, the '796 patent, the '797 patent, the '908 patent, the '568 patent, the '887 patent, the '397 patent, the '398 patent, the '399 patent, the '021 patent, and the '384 patent (the "patents-in-suit").

(b) A judgment that the patents-in-suit are valid and enforceable;

(c) 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;

(d) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 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;

(e) 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;

(f) 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);

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

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

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

SHAW KELLER LLP

/s/ John W. Shaw

John W. Shaw (No. 3362)

Karen E. Keller (No. 4489)

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

kkeller@shawkeller.com

*Attorneys for Teva Pharmaceuticals
International GmbH, Cephalon, Inc., and
Eagle Pharmaceuticals, Inc.*

OF COUNSEL:

David I. Berl

Adam D. Harber

Martha C. Kidd

Shaun P. Mahaffy

WILLIAMS & CONNOLLY LLP

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

*Attorneys for Teva Pharmaceuticals
International GmbH and Cephalon, Inc.*

OF COUNSEL:

Daniel G. Brown

LATHAM & WATKINS LLP

885 Third Avenue

New York, NY 10022

(212) 906-1200

Kenneth G. Schuler

Marc N. Zubick

LATHAM & WATKINS LLP

330 North Wabash Avenue, Suite 2800

Chicago, IL 60611

(312) 876-7700

Attorneys for Eagle Pharmaceuticals, Inc.

Dated: August 24, 2017