IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
SLAYBACK PHARMA LLC,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by its attorneys, for its 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, that arises out of the submission of Abbreviated New Drug Application ("ANDA") No. 212230 by Slayback Pharma LLC ("Slayback" or "Defendant") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL) ("Bendamustine Hydrochloride Injection") prior to the expiration of Plaintiff's U.S. Patent Nos. 8,609,707 ("the '707 patent"); 9,265,831 ("the '831 patent"); 9,572,796 ("the '796 patent"); 9,572,797 ("the '797 patent"); and 10,010,533 ("the '533 patent") (collectively, "the Patents-in-Suit").

PARTIES

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

3. On information and belief, Defendant Slayback Pharma LLC is a corporation organized and existing under the laws of Delaware, with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08550.

JURISDICTION AND VENUE

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

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

6. 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 Slayback.

7. This Court has personal jurisdiction over Slayback because, upon information and belief, Slayback is a corporation organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware. This Court has personal jurisdiction over Slayback for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. In addition, this Court has personal jurisdiction over Slayback because, on information and belief, Slayback has engaged in a persistent course of conduct within Delaware

by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

9. Further, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback has filed ANDA No. 212230 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in ANDA No. 212230 in the United States, including in Delaware; and (2) Slayback will market, distribute, offer for sale, and/or sell the product described in ANDA No. 212230 in the United States, including in Delaware, upon approval of ANDA No. 212230, and will derive substantial revenue from the use or consumption of the product described in ANDA No. 212230 in the State of Delaware. *See Acorda Therapeutics Inc. v. Hospira Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if ANDA No. 212230 is approved, the product described in ANDA No. 212230 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.

10. The Court also has personal jurisdiction over Slayback 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 Eagle, which is a Delaware corporation.

11. Slayback has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has asserted counterclaims in such cases. *See, e.g.*, *Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma Ltd. Liability Co.*, No.

17-01154-GMS, D.I. 11 (D. Del. Sept. 29, 2017); *Teva Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma., Inc.*, No. 18-cv-00117, D.I. 9 (D. Del. Feb. 12, 2018).

12. For at least the above reasons, it would not be unfair or unreasonable for Slayback to litigate this action in this District, and there is personal jurisdiction over Slayback for purposes of this action.

BACKGROUND

13. Bendamustine Hydrochloride Injection, 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.

14. Eagle is the holder of New Drug Application ("NDA") No. 205580 for Bendamustine Hydrochloride Injection, which NDA has been approved by the FDA.

15. The '707 patent, entitled "Formulations of Bendamustine" (Exhibit A hereto), was duly and legally issued on December 17, 2013. Eagle is the owner and assignee of the '707 patent. The '707 patent has been listed in connection with Bendamustine Hydrochloride Injection in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

16. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit B hereto), was duly and legally issued on February 23, 2016. Eagle is the owner and assignee of the '831 patent. The '831 patent has been listed in connection with Bendamustine Hydrochloride Injection in the Orange Book.

17. The ’796 patent, entitled “Formulations of Bendamustine” (Exhibit C hereto), was duly and legally issued on February 21, 2017. Eagle is the owner and assignee of the ’796 patent. The ’796 patent has been listed in connection with Bendamustine Hydrochloride Injection in the Orange Book.

18. The ’797 patent, entitled “Formulations of Bendamustine” (Exhibit D hereto), was duly and legally issued on February 21, 2017. Eagle is the owner and assignee of the ’797 patent. The ’797 patent has been listed in connection with Bendamustine Hydrochloride Injection in the Orange Book.

19. The ’533 patent, entitled “Formulations of Bendamustine” (Exhibit E hereto), was duly and legally issued on July 3, 2018. Eagle is the owner and assignee of the ’533 patent. The ’533 patent has been listed in connection with Bendamustine Hydrochloride Injection in the Orange Book.

INFRINGEMENT BY SLAYBACK

20. By letters dated August 8 and 9, 2018 (the “Notice Letters”), Slayback notified Eagle pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that Slayback had submitted to the FDA ANDA No. 212230, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of a generic Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL) (“Slayback’s ANDA Product”) prior to the expiration of the Patents-in-Suit. Upon information and belief, Slayback’s ANDA Product is a generic version of Bendamustine Hydrochloride Injection, containing the same or equivalent ingredients in the same or equivalent amounts.

21. The purpose of Slayback's submission of ANDA No. 212230 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product prior to the expiration of the Patents-in-Suit.

22. In the Notice Letters, Slayback also notified Eagle that, as part of its ANDA No. 212230, Slayback had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification") with respect to each of the Patents-in-Suit. Upon information and belief, Slayback submitted Paragraph IV Certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA in connection with ANDA No. 212230 asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Slayback's ANDA Product, or alternatively, that these patents are invalid or unenforceable.

23. In the Notice Letters, Slayback stated that the active ingredient of Slayback's ANDA Product is bendamustine hydrochloride.

24. In the Notice Letters, Slayback stated that the proposed dosage strength of Slayback's ANDA Product is 25 mg/mL.

25. Upon information and belief, Slayback's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as Bendamustine Hydrochloride Injection.

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

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

28. This action is being commenced before the expiration of forty-five days from the date of the Eagle's receipt of each of the Notice Letters.

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

29. Eagle incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. Slayback's submission of ANDA No. 212230 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback'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). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's ANDA Product or induces or contributes to such conduct, said actions would constitute infringement of the '707 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

31. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

32. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

33. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the '707 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of

each of the steps of one or more claims of the ’707 patent, either literally or under the doctrine of equivalents.

34. Upon information and belief, the use of Slayback’s ANDA Product in accordance with and as directed by Slayback’s proposed labeling for that product would infringe one or more claims of the ’707 patent, either literally or under the doctrine of equivalents.

35. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the ’707 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

36. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the ’707 patent after approval of ANDA No. 212230.

37. The foregoing actions by Slayback constitute and/or will constitute infringement of the ’707 patent, active inducement of infringement of the ’707 patent, and/or contribution to the infringement by others of the ’707 patent.

38. Upon information and belief, Slayback 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/or contributing to the infringement by others of the ’707 patent.

39. Unless Slayback 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, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

40. Eagle incorporates each of the preceding paragraphs 1–39 as if fully set forth herein.

41. Slayback's submission of ANDA No. 212230 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback'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). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's ANDA Product, said actions would constitute infringement of the '831 patent under 35 U.S.C. § 271(a).

42. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

43. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

44. The foregoing actions by Slayback constitute and/or will constitute infringement of the '831 patent.

45. Upon information and belief, Slayback 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.

46. Unless Slayback is enjoined from infringing the '831 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

47. Eagle incorporates each of the preceding paragraphs 1–46 as if fully set forth herein.

48. Slayback's submission of ANDA No. 212230 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback'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). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's ANDA Product or induces or contributes to such conduct, said actions would constitute infringement of the '796 patent under 35 U.S.C. §§ 271 (a), 271(b), and/or 271(c).

49. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

50. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

51. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the '796 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

52. Upon information and belief, the use of Slayback's ANDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

53. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

54. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '796 patent after approval of ANDA No. 212230.

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

56. Upon information and belief, Slayback 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/or contributing to the infringement by others of the '796 patent.

57. Unless Slayback 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, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

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

59. Slayback's submission of ANDA No. 212230 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback'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). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's ANDA Product or induces or contributes to such conduct, said actions would constitute infringement of the '797 patent under 35 U.S.C. § 271(b) and/or 271(c).

60. The use of Slayback's ANDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

61. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the '797 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

62. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

63. Upon information and belief, the use of Slayback's ANDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

64. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

65. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '797 patent after approval of ANDA No. 212230.

66. The foregoing actions by Slayback constitute and/or will constitute active inducement of infringement of the '797 patent and/or contribution to the infringement by others of the '797 patent.

67. Upon information and belief, Slayback has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '797 patent and/or contributing to the infringement by others of the '797 patent.

68. Unless Slayback is enjoined from actively inducing infringement of the '797 patent and contributing to the infringement by others of the '797 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

69. Eagle incorporates each of the preceding paragraphs 1–68 as if fully set forth herein.

70. Slayback's submission of ANDA No. 212230 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product prior to the expiration of the '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's ANDA Product, said actions would constitute infringement of the '533 patent under 35 U.S.C. § 271 (a).

71. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '533 patent, either literally or under the doctrine of equivalents.

72. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

73. The foregoing actions by Slayback constitute and/or will constitute infringement of the '533 patent.

74. Upon information and belief, Slayback has acted with full knowledge of the '533 patent and without a reasonable basis for believing that it would not be liable for infringing the '533 patent.

75. Unless Slayback is enjoined from infringing the '533 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

76. Eagle incorporates each of the preceding paragraphs 1–75 as if fully set forth herein.

77. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

78. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the '707 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

79. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

80. Upon information and belief, the use of Slayback's ANDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

81. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '707 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

82. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the ’707 patent after approval of ANDA No. 212230.

83. The foregoing actions by Slayback constitute and/or will constitute infringement of the ’707 patent, active inducement of infringement of the ’707 patent, and/or contribution to the infringement by others of the ’707 patent.

84. Upon information and belief, Slayback 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/or contributing to the infringement by others of the ’707 patent.

85. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback’s manufacture, use, sale, offer for sale, or importation into the United States of Slayback’s ANDA Product with its proposed labeling according to ANDA No. 212230 will infringe one or more claims of the ’707 patent and whether one or more claims of the ’707 patent are valid and enforceable.

86. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and/or contribute to the infringement by others of the ’707 patent and that the claims of the ’707 patent are valid and enforceable.

87. Slayback 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 Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

88. Eagle incorporates each of the preceding paragraphs 1–87 as if fully set forth herein.

89. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product would infringe one or more claims of the ’831 patent, either literally or under the doctrine of equivalents.

90. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

91. Upon information and belief, Slayback 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.

92. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback’s manufacture, use, sale, offer for sale, or importation into the United States of Slayback’s ANDA Product with its proposed labeling according to ANDA No. 212230 will infringe one or more claims of the ’831 patent and whether one or more claims of the ’831 patent are valid.

93. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback’s ANDA Product with its

proposed labeling would infringe the claims of the ’831 patent and that the claims of the ’831 patent are valid.

94. Slayback should be enjoined from infringing the ’831 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

95. Eagle incorporates each of the preceding paragraphs 1–94 as if fully set forth herein.

96. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product would infringe one or more claims of the ’796 patent, either literally or under the doctrine of equivalents.

97. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the ’796 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the ’796 patent, either literally or under the doctrine of equivalents.

98. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

99. Upon information and belief, the use of Slayback’s ANDA Product in accordance with and as directed by Slayback’s proposed labeling for that product would infringe one or more claims of the ’796 patent, either literally or under the doctrine of equivalents.

100. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

101. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '796 patent after approval of ANDA No. 212230.

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

103. Upon information and belief, Slayback 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/or contributing to the infringement by others of the '796 patent.

104. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback's manufacture, use, sale, offer for sale, or importation into the United States of Slayback's ANDA Product with its proposed labeling according to ANDA No. 212230 will infringe one or more claims of the '796 patent and whether one or more claims of the '796 patent are valid and enforceable.

105. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and/or contribute to the

infringement by others of the ’796 patent and that the claims of the ’796 patent are valid and enforceable.

106. Slayback 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 Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

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

107. Eagle incorporates each of the preceding paragraphs 1–106 as if fully set forth herein.

108. Upon information and belief, the use of Slayback’s ANDA Product would infringe one or more claims of the ’797 patent, either literally or under the doctrine of equivalents.

109. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback ANDA Product within the scope of one or more claims of the ’797 patent, either literally or under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the ’797 patent, either literally or under the doctrine of equivalents.

110. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

111. Upon information and belief, the use of Slayback’s ANDA Product in accordance with and as directed by Slayback’s proposed labeling for that product would infringe one or more claims of the ’797 patent, either literally or under the doctrine of equivalents.

112. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the ’797 patent when ANDA No. 212230 is approved, and plans and intends to, and will, do so after approval.

113. Upon information and belief, Slayback 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 unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the ’797 patent after approval of ANDA No. 212230.

114. The foregoing actions by Slayback constitute and/or will constitute active inducement of infringement of the ’797 patent and/or contribution to the infringement by others of the ’797 patent.

115. Upon information and belief, Slayback has acted with full knowledge of the ’797 patent and without a reasonable basis for believing that it would not be liable for actively inducing infringement of the ’797 patent and/or contributing to the infringement by others of the ’797 patent.

116. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback’s manufacture, use, sale, offer for sale, or importation into the United States of Slayback’s ANDA Product with its proposed labeling according to ANDA No. 212230 will infringe one or more claims of the ’797 patent and whether one or more claims of the ’797 patent are valid.

117. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback’s ANDA Product with its

proposed labeling would 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.

118. Slayback should be enjoined from actively inducing infringement of the ’797 patent and contributing to the infringement by others of the ’797 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,010,533

119. Eagle incorporates each of the preceding paragraphs 1–118 as if fully set forth herein.

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

121. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 212230.

122. Upon information and belief, Slayback has acted with full knowledge of the ’533 patent and without a reasonable basis for believing that it would not be liable for infringing the ’533 patent.

123. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback’s manufacture, use, sale, offer for sale, or importation into the United States of Slayback’s ANDA Product with its proposed labeling according to ANDA No. 212230 will infringe one or more claims of the ’533 patent and whether one or more claims of the ’533 patent are valid.

124. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's ANDA Product with its proposed labeling would infringe the claims of the '533 patent and that the claims of the '533 patent are valid.

125. Slayback should be enjoined from infringing the '533 patent; otherwise Eagle will suffer irreparable injury. Eagle haves no adequate remedy at law.

WHEREFORE, Eagle requests the following relief:

(a) A judgment that Slayback has infringed, will infringe, and/or will induce and contribute to infringement of the '707 patent, the '831 patent, the '796 patent, the '797 patent, and the '533 patent.

(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 Slayback to make, use, offer for sale, sell, market, distribute, or import Slayback'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 Slayback, 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 Slayback'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 Slayback'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 Eagle's damages or other monetary relief to compensate Eagle if Slayback engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Slayback'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 Slayback is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

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

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

/s/ Karen E. Keller

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