**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF NORTH CAROLINA**

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| EAGLE PHARMACEUTICALS, INC.,<br><br>Plaintiff,<br><br>v.<br><br>ACCORD HEALTHCARE INC., ACCORD HEALTHCARE LTD., and INTAS PHARMACEUTICALS LTD.,<br><br>Defendants. | Civil Action No.: 5:24-cv-95<br><br>**COMPLAINT** |

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., which arises out of Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd.'s (collectively, "Accord's") submission of New Drug Application ("NDA") No. 216987 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of BELRAPZO® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to the expiration of Eagle's U.S. Patent Nos. 11,844,783 (the "'783 patent") and 11,872,214 (the "'214 patent") (collectively, the "Patents-in-Suit"), attached hereto as Exhibits A and B respectively.

## PARTIES

2. Plaintiff Eagle 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 Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, with a place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617. On information and belief, Accord Healthcare Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including North Carolina.

4. On information and belief, Defendant Accord Healthcare Ltd. is a corporation organized and existing under the laws of the United Kingdom, with a place of business at Sage House, 319 Pinner Road North Harrow, Middlesex London HA1 4HF England, United Kingdom. On information and belief, Accord Healthcare Ltd. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products, including through various affiliates, including Accord Healthcare Inc., throughout the United States, including North Carolina.

5. On information and belief, Defendant Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Republic of India, with a place of business at Corporate House, Near Sola Bridge S. G. Highway, Thaltej Ahmedabad, Gujarat 380054, Republic of India. On information and belief, Intas Pharmaceuticals Ltd. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products, including through various operating subsidiaries, including Accord Healthcare Inc. and Accord Healthcare Ltd., throughout the United States, including North Carolina.

6. On information and belief, records from the North Carolina Secretary of State reflect that Intas Pharmaceuticals Ltd. was and is authorized to do business in North Carolina, and that Intas Pharmaceuticals Ltd. has a corporate office located at 1009 Slater Road, Suite 210B, Durham, North Carolina, 27703.

7. On information and belief, Accord Healthcare Inc. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd. and the U.S. agent for Intas Pharmaceuticals Ltd.

8. On information and belief, Accord Healthcare Ltd. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

9. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. acted in concert to prepare and submit Accord's NDA to FDA.

10. On information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare Ltd. actively encouraged, recommended, and promoted that Accord Healthcare Inc. prepare and submit Accord's NDA to FDA and knew that the filing of Accord's NDA would infringe the Patents-in-Suit, including because Intas Pharmaceuticals Ltd. and Accord Healthcare Ltd. knew that Accord's NDA would include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) with respect to the Patents-in-Suit.

11. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. know and intend that upon approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will manufacture Accord's NDA Product; and Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will directly or indirectly market, sell, and distribute Accord's NDA Product throughout the United States, including in North Carolina. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. are agents of each other and/or operate in

concert as integrated parts of the same business group, including with respect to Accord's NDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. participated, assisted, and cooperated in carrying out the acts complained about herein.

12. On information and belief, following any FDA approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will distribute and sell Accord's NDA Product throughout the United States, including within North Carolina.

## JURISDICTION AND VENUE

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

14. 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 Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd.

15. This Court has personal jurisdiction over Accord Healthcare Inc. because, among other things, Accord Healthcare Inc., itself and through its parent Intas Pharmaceuticals Ltd. and affiliate Accord Healthcare Ltd., has purposely availed itself of the benefits and protections of North Carolina's laws such that it should reasonably anticipate being haled into court here. On information and belief, Accord Healthcare Inc. is incorporated and headquartered in Raleigh, North Carolina. In addition, on information and belief, Accord Healthcare Inc., itself and through its parent Intas Pharmaceuticals Ltd. and affiliate Accord Healthcare Ltd., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in North Carolina, and therefore transacts business within North Carolina relating to

Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within North Carolina.

16. In addition, this Court also has personal jurisdiction over Accord Healthcare Inc. because, on information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. are alter egos of each other. Therefore, Intas Pharmaceuticals Ltd.'s and Accord Healthcare Ltd.'s activities in North Carolina are attributable to Accord Healthcare Inc.

17. This Court has personal jurisdiction over Intas Pharmaceuticals Ltd. because, among other things, it has purposely availed itself of the benefits and protections of North Carolina's laws such that it should reasonably anticipate being haled into court here. On information and belief, Intas Pharmaceuticals Ltd., itself and through its subsidiaries Accord Healthcare Inc. and Accord Healthcare Ltd., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in North Carolina, and therefore transacts business within North Carolina relating to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within North Carolina.

18. In addition, this Court has personal jurisdiction over Intas Pharmaceuticals Ltd. because, on information and belief, Intas Pharmaceuticals Ltd. directs and controls Accord Healthcare Inc. and Accord Healthcare Ltd.; and Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. are alter egos of each other. Therefore, Accord Healthcare Inc.'s and Accord Healthcare Ltd.'s activities in North Carolina are attributable to Intas Pharmaceuticals Ltd.

19. This Court has personal jurisdiction over Accord Healthcare Ltd. because, among other things, it has purposely availed itself of the benefits and protections of North Carolina's laws such that it should reasonably anticipate being haled into court here. On information and belief,

Accord Healthcare Ltd., itself and through its affiliate Accord Healthcare Ltd. and parent Intas Pharmaceuticals Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in North Carolina, and therefore transacts business within North Carolina relating to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within North Carolina.

20. In addition, this Court has personal jurisdiction over Accord Healthcare Ltd. because, on information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. are alter egos of each other. Therefore, Accord Healthcare Inc.'s and Intas Pharmaceuticals Ltd.'s activities in North Carolina are attributable to Accord Healthcare Ltd.

21. In addition, this Court also has personal jurisdiction over Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. because, among other things, on information and belief: (1) Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. filed Accord's NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's NDA Product in the United States, including in North Carolina; and (2) upon approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will market, distribute, offer for sale, sell, and/or import Accord's NDA Product in the United States, including in North Carolina, and will derive substantial revenue from the use or consumption of Accord's NDA Product in North Carolina. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Accord's NDA, Accord's NDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in North Carolina; prescribed by physicians practicing in North Carolina; dispensed by pharmacies

located within North Carolina; and/or used by patients in North Carolina, all of which would have a substantial effect on North Carolina.

22. For the above reasons, it would not be fundamentally unfair or unreasonable for Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) with respect to Accord Healthcare Inc., at least because, on information and belief, Accord Healthcare Inc. is incorporated in North Carolina and therefore resides there for purposes of venue.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Intas Pharmaceuticals Ltd., at least because, on information and belief, Intas Pharmaceuticals Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

25. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Accord Healthcare Ltd., at least because, on information and belief, Accord Healthcare Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

## BACKGROUND

26. BELRAPZO®, 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.

27. Eagle is the holder of NDA No. 205580 for BELRAPZO®, which has been approved by the FDA.

28. The ’783 patent, entitled “Formulations of Bendamustine” (Exhibit A hereto), was duly and legally issued on November 29, 2023. Eagle is the owner and assignee of the ’783 patent. Eagle timely submitted the ’783 patent to be listed in connection with BELRAPZO® in the FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the “Orange Book.”

29. Claim 1 of the ’783 patent recites: A method of treating leukemia in a human in need thereof comprising

providing a liquid bendamustine-containing composition comprising

bendamustine, or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is from about 20 mg/mL to about 60 mg/mL;

a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and

a stabilizing amount of an antioxidant;

wherein the total impurities in the liquid bendamustine-containing composition resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C;

diluting the liquid bendamustine containing composition; and

intravenously administering the diluted composition to the human.

30. BELRAPZO is a product that falls within the ambit of at least claim 1 of the ’783 patent.

31. The ’214 patent, entitled “Formulations of Bendamustine” (Exhibit B hereto), was duly and legally issued on January 16, 2024. Eagle is the owner and assignee of the ’214 patent.

Eagle timely submitted the ’214 patent to be listed in connection with BELRAPZO® in the Orange Book.

32. Claim 1 of the ’214 patent recites: A sterile vial containing a liquid bendamustine-containing composition comprising

about 100 mg of bendamustine or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is about 25 mg/mL;

a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and

a stabilizing amount of antioxidant,

wherein the total impurities resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C.

33. BELRAPZO is a product that falls within the ambit of at least claim 1 of the ’214 patent.

**INFRINGEMENT BY ACCORD**

34. By letter dated January 4, 2024 (“Accord’s Notice Letter”), Accord notified Eagle that it had filed a Paragraph IV Certification with respect to the ’783 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord’s NDA Product prior to the expiration of the Patents-in-Suit.

35. The purpose of Accord’s submission of Accord’s NDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Accord’s NDA Product prior to the expiration of the Patents-in-Suit.

36. Upon information and belief, Accord's NDA Product relies on data from bioavailability and/or bioequivalence studies contained in the approved labeling for BELRAPZO®. BELRAPZO® is approved for a 24-month shelf life. Accord's Notice Letter does not identify any difference in stability between Accord's NDA Product and BELRAPZO® and, upon information and belief, Accord's NDA Product has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patents-in-Suit.

37. In Accord's Notice Letter, Accord stated that the active ingredient of Accord's NDA Product is bendamustine hydrochloride.

38. In Accord's Notice Letter, Accord stated that Accord's NDA Product contains 100 mg/4 mg (25 mg/mL) bendamustine hydrochloride.

39. In Accord's Notice Letter, Accord did not disclose the composition of Accord's NDA product and furnish samples, data, or other information sufficient to confirm independently the exact composition of Accord's NDA product and assess the properties and functions of Accord's NDA Product.

40. Upon information and belief, Accord's NDA Product will be used for the treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma, which are types of cancer.

41. Upon information and belief, Accord's NDA Product contains polyethylene glycol. Upon information and belief, Accord's NDA Product also contains a stabilizing amount of an antioxidant.

42. Upon information and belief, Accord's NDA Product has less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC at a wavelength of 223 nm after at least 15 months at a temperature of from about 5 °C to about 25 °C.

## COUNT I – INFRINGEMENT OF U.S. PATENT NO. 11,844,783

43. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

44. Accord's submission of NDA No. 216987 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's NDA Product prior to the expiration of the '783 patent, was an act of infringement of the '783 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product would infringe one or more claims of the '783 patent, including but not limited to claim 1, either literally and/or under the doctrine of equivalents.

46. Upon information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product with its proposed labeling upon FDA approval of NDA No. 216987.

47. Upon information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '783 patent.

48. Upon information and belief, Accord plans and intends to, and will, actively induce infringement of the '783 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

49. Upon information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent and that Accord's NDA Product and its proposed labeling are not suitable for substantial non-infringing

use. On information and belief, Accord's plans and intends to, and will, contribute to infringement of the '783 patent after approval of Accord's NDA.

50. The foregoing actions by Accord constitute and/or will constitute infringement of the '783 patent, active inducement of infringement of the '783 patent, and contribution to the infringement by others of the '783 patent.

51. Unless Accord is enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

**COUNT II – INFRINGEMENT OF U.S. PATENT NO. 11,872,214**

52. Accord's submission of NDA No. 216987 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's NDA Product prior to the expiration of the '214 patent, was an act of infringement of the '214 patent under 35 U.S.C. § 271(e)(2)(A).

53. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product would infringe one or more claims of the '214 patent, including but not limited to claim 1, either literally and/or under the doctrine of equivalents.

54. Upon information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product with its proposed labeling upon FDA approval of NDA No. 216987.

55. Upon information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '214 patent.

56. Upon information and belief, Accord plans and intends to, and will, actively induce infringement of the ’214 patent when Accord’s NDA is approved, and plans and intends to, and will, do so after approval.

57. Upon information and belief, Accord knows that Accord’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’214 patent and that Accord’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Accord plans and intends to, and will, contribute to infringement of the ’214 patent after approval of Accord’s NDA.

58. The foregoing actions by Accord constitute and/or will constitute infringement of the ’214 patent, active inducement of infringement of the ’214 patent, and contribution to the infringement by others of the ’214 patent.

59. Unless Accord is enjoined from infringing the ’214 patent, actively inducing infringement of the ’214 patent, and contributing to the infringement by others of the ’214 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

**COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,844,783**

60. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

61. Upon information and belief, Accord has knowledge of the ’783 patent and/or the application leading to the ’783 patent, Application No. 18/081,238.

62. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord’s NDA Product would infringe one or more claims of the ’783 patent, including but not limited to claim 1, either literally or under the doctrine of equivalents.

63. Upon information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product with its proposed labeling upon FDA approval of NDA No. 216987.

64. Upon information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '783 patent, including but not limited to claim 1.

65. Upon information and belief, Accord plans and intends to, and will, actively induce infringement of the '783 patent when NDA No. 216987 is approved, and plans and intends to, and will, do so after approval.

66. Upon information and belief, Accord knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Accord plans and intends to, and will, contribute to infringement of the '783 patent after approval of NDA No. 216987.

67. The foregoing actions by Accord constitute and/or will constitute infringement of the '783 patent, active inducement of infringement of the '783 patent, and contribution to the infringement by others of the '783 patent.

68. Upon information and belief, Accord has acted without a reasonable basis for believing that it would not be liable for infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent.

69. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Accord regarding whether Accord's manufacture, use, sale, offer for sale, or

importation into the United States of Accord's NDA Product with its proposed labeling according to NDA No. 216987 will infringe one or more claims of the '783 patent.

70. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Accord's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '783 patent.

71. Accord should be enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

**COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,872,214**

72. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

73. Upon information and belief, Accord has knowledge of the '214 patent and/or the application leading to the '214 patent, Application No. 18/081,251.

74. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product would infringe one or more claims of the '214 patent, including but not limited to claim 1, either literally or under the doctrine of equivalents.

75. Upon information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product with its proposed labeling upon FDA approval of NDA No. 216987.

76. Upon information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord's proposed labeling for that product would infringe one or more claims of the '214 patent, including but not limited to claim 1.

77. Upon information and belief, Accord plans and intends to, and will, actively induce infringement of the ’214 patent when NDA No. 216987 is approved, and plans and intends to, and will, do so after approval.

78. Upon information and belief, Accord knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’214 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Accord plans and intends to, and will, contribute to infringement of the ’214 patent after approval of NDA No. 216987.

79. The foregoing actions by Accord constitute and/or will constitute infringement of the ’214 patent, active inducement of infringement of the ’214 patent, and contribution to the infringement by others of the ’214 patent.

80. Upon information and belief, Accord has acted without a reasonable basis for believing that it would not be liable for infringing the ’214 patent, actively inducing infringement of the ’214 patent, and contributing to the infringement by others of the ’214 patent.

81. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Accord regarding whether Accord’s manufacture, use, sale, offer for sale, or importation into the United States of Accord’s NDA Product with its proposed labeling according to NDA No. 216987 will infringe one or more claims of the ’214 patent.

82. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Accord’s NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’214 patent.

83. Accord should be enjoined from infringing the ’214 patent, actively inducing infringement of the ’214 patent, and contributing to the infringement by others of the ’214 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

## PRAYER FOR RELIEF

**WHEREFORE**, Eagle requests the following relief:

(a) A judgment that Accord has infringed, will infringe, and will induce and contribute to infringement of the Patents-in-Suit;

(b) A judgement 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 Accord to make, use, offer for sale, sell, market, distribute, or import Accord’s NDA 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 expiration date 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 Accord, 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 Accord’s NDA 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 expiration date 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 Accord’s NDA 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 Accord engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Accord's NDA 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 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.

Dated: February 16, 2024

By: /s/Melanie Black Dubis
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