

**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. _____
)	
ACCORD HEALTHCARE INC., ACCORD)	
HEALTHCARE LTD., and)	
INTAS PHARMACEUTICALS LTD.,)	
)	
Defendants.)	
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COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH (“Teva Pharmaceuticals”), Cephalon, Inc. (“Cephalon”) (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, 35 U.S.C., 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., 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. 215749 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 Bendeka® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to the expiration of 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”);

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”); 9,579,384 (the “384 patent”), 10,010,533 (the “533 patent”); and 10,052,385 (the “385 patent”) (collectively, the “Patents-in-Suit”).

PARTIES

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

3. Plaintiff Cephalon is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

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

5. 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 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703. 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 Delaware.

6. On information and belief, Defendant Accord Healthcare 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 380 054, Republic of India. 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 Delaware.

7. 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 Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, Gujarat 380 009, 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 Delaware.

8. 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.

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

10. 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.

11. 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.

12. 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 Delaware. 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.

13. On information and belief, following any FDA approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will act in concert to distribute and sell Accord's NDA Product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

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

15. 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.

16. 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 purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. 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 Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

17. In addition, this Court 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 Delaware are attributable to Accord Healthcare Inc.

18. This Court has personal jurisdiction over Intas Pharmaceuticals Ltd. because, among other things, it has purposely availed itself of the benefits and protections of Delaware'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 Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

19. 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., Accord Healthcare Ltd., are alter egos of each other. Therefore, Accord Healthcare Inc.'s and Accord Healthcare Ltd.'s activities in Delaware are attributable to Intas Pharmaceuticals Ltd.

20. This Court has personal jurisdiction over Accord Healthcare Ltd. because, among other things, it has purposely availed itself of the benefits and protections of Delaware'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 Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

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

22. 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 Delaware; 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 Delaware, and will derive substantial revenue from the use or consumption of Accord's NDA

Product in Delaware. *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 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.

23. In addition, this Court has personal jurisdiction over Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. because they have 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.

24. In addition, this Court has personal jurisdiction over Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. because they regularly engage in patent litigation concerning Accord's NDA or Abbreviated New Drug Application ("ANDA") Products in this District, have previously consented to personal jurisdiction in this District, and/or have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District.¹

25. In addition, this Court has personal jurisdiction over Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. because, by e-mail dated June 23,

¹ *See, e.g., Purdue Pharma LP et al. v. Accord Healthcare Inc. et al.*, C.A. No. 20-1362-RGA-SRF (Mar. 12, 2021 D. Del.), D.I. 14; *Merck Sharp & Dohme Corp. v. Accord Healthcare Inc. et al.*, C.A. No. 19-2192-RGA (Jan. 24, 2020 D. Del.), D.I. 13; *Amgen Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-956-MSG (Sept. 18, 2018 D. Del.), D.I. 10; *Novartis Pharm. Co. v. Accord Healthcare Inc. et al.*, C.A. No. 18-1043-LPS (D. Del. Aug. 8, 2018), D.I. 46.

2021, Accord confirmed that it will not oppose jurisdiction in the District of Delaware for purposes of this action, and thus has consented to this Court's exercise of personal jurisdiction for purposes of this action.

26. 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.

VENUE

27. Plaintiffs incorporate each of the proceeding paragraphs 1–26 as if fully set forth herein.

28. Venue is proper in this District 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 subject to personal jurisdiction in this District and has previously consented to venue in this District.²

29. 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 and has previously consented to venue in this District.³

30. 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

² See *supra* ¶ 26 n.1.

³ See *supra* ¶ 26 n.1.

Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction and has previously consented to venue in this District.⁴

31. In addition, venue is proper in this District with respect to Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. because, by e-mail dated June 23, 2021, Accord confirmed that it will not oppose venue in the District of Delaware for purposes of this action, and thus has consented to venue in this District for purposes of this action.

BACKGROUND

32. Bendeka[®], which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with (1) chronic lymphocytic leukemia and (2) indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

33. Eagle is the holder of NDA No. 208194 for Bendeka[®], which has been approved by FDA.

34. The '707 patent, entitled "Formulations of Bendamustine" (Exhibit A), 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.

35. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit B), 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.

⁴ See *supra* ¶ 26 n.1.

36. The '796 patent, entitled "Formulations of Bendamustine" (Exhibit C), 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.

37. The '797 patent, entitled "Formulations of Bendamustine" (Exhibit D), 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.

38. The '908 patent, entitled "Formulations of Bendamustine" (Exhibit E), 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.

39. The '568 patent, entitled "Formulations of Bendamustine" (Exhibit F), 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.

40. The '887 patent, entitled "Formulations of Bendamustine" (Exhibit G), 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.

41. The '397 patent, entitled "Formulations of Bendamustine" (Exhibit H), 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.

42. The '398 patent, entitled "Formulations of Bendamustine" (Exhibit I), 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.

43. The '399 patent, entitled "Formulations of Bendamustine" (Exhibit J), 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.

44. The '021 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit K), 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.

45. The '384 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit L), 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.

46. The '533 patent, entitled "Formulations of Bendamustine" (Exhibit M), was duly and legally issued on July 3, 2018. Eagle Pharmaceuticals, Inc. is the owner and assignee of

the '533 patent, subject to the exclusive license referenced herein. The '533 patent has been listed in connection with Bendeka[®] in the Orange Book.

47. The '385 patent, entitled “Formulations of Bendamustine” (Exhibit N), was duly and legally issued on August 21, 2018. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '385 patent, subject to the exclusive license referenced herein. The '385 patent has been listed in connection with Bendeka[®] in the Orange Book.

48. On or around February 13, 2015, Cephalon executed an exclusive license (the “Eagle License”) to, among other things, the '707 patent, U.S. Patent Application No. 14/031,879 (which later issued as the '831 patent); U.S. Patent Application No. 13/838,090 (which later issued as the '908 patent), U.S. 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, '384, '533, and '385 patents), for the commercialization of Eagle’s bendamustine hydrochloride rapid infusion product, EP-3102, which became Bendeka[®]. The Eagle License provides Cephalon the right to sue for infringement of the licensed patents in the event of, among other things, the filing of an NDA that makes reference to Bendeka[®] and seeks approval before expiry of a licensed patent.

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

INFRINGEMENT BY ACCORD

50. By letter dated May 17, 2021 (“Accord’s Notice Letter”), Accord Healthcare Inc. notified Teva and Eagle that it had filed a Paragraph IV Certification with respect to the Patents-in-Suit and was seeking approval from 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. On information and belief, Accord's NDA contains a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Accord's NDA Product, or alternatively, that the Patents-in-Suit are invalid.

51. 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.

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

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

54. 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.

55. On information and belief, Accord's NDA Product contains bendamustine, propylene glycol, polyethylene glycol, and monothioglycerol, or equivalent ingredients, in the same or equivalent amounts as Bendeka®.

56. On information and belief, the proposed labeling for Accord's NDA Product recommends, encourages, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

57. On information and belief, the proposed labeling for Accord's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m² to patients with chronic lymphocytic leukemia.

58. On information and belief, the proposed labeling for Accord's NDA Product recommends, encourages, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

59. On information and belief, the proposed labeling for Accord's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m² to patients with indolent B-cell non-Hodgkin lymphoma.

60. On information and belief, the proposed labeling for Accord's NDA Product recommends, encourages, instructs, and/or promotes the administration of Accord's NDA Product in a volume of about 50 mL or less over a time period of about 10-minutes or less.

61. In an exchange of correspondence, counsel for Teva and counsel for Accord discussed the terms of Accord's Offer for Confidential Access pursuant to 21 U.S.C. § 355(b)(3). The parties did not agree on terms under which Teva could review, among other things, Accord's NDA and certain portions of the Drug Master File referred to therein, and Accord refused to produce samples of Accord's NDA product and other internal documents and materials relevant to infringement. In addition, Accord's Offer for Confidential Access placed unreasonable restrictions on the extent to which Teva could access the documents and materials subject to the offer. Without all of the materials requested by Teva, including samples of Accord's NDA product, which Accord refused to produce, Teva could not confirm, and cannot confirm, the exact composition and properties of Accord's NDA product. Accord's filing of its NDA seeking

approval to market a generic version of Bendeka® before expiry of the patents asserted herein constitutes an act of infringement.

62. On June 14, 2021, counsel for Teva notified counsel for Accord that it was Teva's understanding that the parties were at an impasse. Counsel for Accord did not contradict that understanding.

63. This action is being commenced before the expiration of forty-five days from the date of the receipt of Accord's Notice Letter.

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

64. Plaintiffs incorporate each of the preceding paragraphs 1–63 as if fully set forth herein.

65. Accord's submission of Accord's NDA 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 '707 patent was an act of infringement of the '707 patent under 35 U.S.C. § 271(e)(2)(A).

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

67. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

68. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '707 patent.

69. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '707 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

70. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 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 '707 patent after approval of Accord's NDA.

71. The foregoing actions by Accord 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.

72. On information and belief, Accord 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.

73. Unless Accord 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 II – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)**

74. Plaintiffs incorporate each of the preceding paragraphs 1–73 as if fully set forth herein.

75. Accord's submission of Accord's NDA 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 '831 patent was an act of infringement of the '831 patent under 35 U.S.C. § 271(e)(2)(A).

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

77. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

78. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '831 patent.

79. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '831 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

80. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 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 '831 patent after approval of Accord's NDA.

81. The foregoing actions by Accord 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.

82. On information and belief, Accord 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.

83. Unless Accord 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 III – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)**

84. Plaintiffs incorporate each of the preceding paragraphs 1–83 as if fully set forth herein.

85. Accord's submission of Accord's NDA 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 '796 patent was an act of infringement of the '796 patent under 35 U.S.C. § 271(e)(2)(A).

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

87. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

88. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '796 patent.

89. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '796 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

90. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 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 '796 patent after approval of Accord's NDA.

91. The foregoing actions by Accord 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.

92. On information and belief, Accord 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.

93. Unless Accord 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 IV – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)**

94. Plaintiffs incorporate each of the preceding paragraphs 1–93 as if fully set forth herein.

95. Accord's submission of Accord's NDA 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 '797 patent was an act of infringement of the '797 patent under 35 U.S.C. § 271(e)(2)(A).

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

97. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

98. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '797 patent.

99. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '797 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

100. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 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 '797 patent after approval of Accord's NDA.

101. The foregoing actions by Accord 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.

102. On information and belief, Accord 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.

103. Unless Accord 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 V – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,034,908 UNDER 35 U.S.C. § 271(e)(2)**

104. Plaintiffs incorporate each of the preceding paragraphs 1–103 as if fully set forth herein.

105. Accord's submission of Accord's NDA 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 '908 patent was an act of infringement of the '908 patent under 35 U.S.C. § 271(e)(2)(A).

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

107. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

108. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '908 patent.

109. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '908 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

110. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 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 '908 patent after approval of Accord's NDA.

111. The foregoing actions by Accord 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.

112. On information and belief, Accord 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.

113. Unless Accord 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 VI – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,144,568 UNDER 35 U.S.C. § 271(e)(2)**

114. Plaintiffs incorporate each of the preceding paragraphs 1–113 as if fully set forth herein.

115. Accord's submission of Accord's NDA 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 '568 patent was an act of infringement of the '568 patent under 35 U.S.C. § 271(e)(2)(A).

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

117. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

118. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '568 patent.

119. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '568 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

120. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 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 '568 patent after approval of Accord's NDA.

121. The foregoing actions by Accord 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.

122. On information and belief, Accord 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.

123. Unless Accord 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 VII – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)**

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

125. Accord's submission of Accord's NDA 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 '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

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

127. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

128. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '887 patent.

129. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '887 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

130. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 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 '887 patent after approval of Accord's NDA.

131. The foregoing actions by Accord 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. On information and belief, Accord 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 Accord 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 VIII – INFRINGEMENT BY ACCORD
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. Accord's submission of Accord's NDA 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 '397 patent was an act of infringement of the '397 patent under 35 U.S.C. § 271(e)(2)(A).

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

137. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

138. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '397 patent.

139. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '397 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

140. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 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 '397 patent after approval of Accord's NDA.

141. The foregoing actions by Accord 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.

142. On information and belief, Accord 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.

143. Unless Accord 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 IX – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,597,398 UNDER 35 U.S.C. § 271(e)(2)**

144. Plaintiffs incorporate each of the preceding paragraphs 1–143 as if fully set forth herein.

145. Accord's submission of Accord's NDA 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 '398 patent was an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

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

147. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

148. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '398 patent.

149. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '398 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

150. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 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 '398 patent after approval of Accord's NDA.

151. The foregoing actions by Accord 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.

152. On information and belief, Accord 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.

153. Unless Accord 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 X – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,597,399 UNDER 35 U.S.C. § 271(e)(2)**

154. Plaintiffs incorporate each of the preceding paragraphs 1–153 as if fully set forth herein.

155. Accord's submission of Accord's NDA 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 '399 patent was an act of infringement of the '399 patent under 35 U.S.C. § 271(e)(2)(A).

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

157. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

158. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '399 patent.

159. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '399 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

160. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 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 '399 patent after approval of Accord's NDA.

161. The foregoing actions by Accord 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.

162. On information and belief, Accord 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.

163. Unless Accord 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 XI – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,000,021 UNDER 35 U.S.C. § 271(e)(2)**

164. Plaintiffs incorporate each of the preceding paragraphs 1–163 as if fully set forth herein.

165. Accord's submission of Accord's NDA 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 '021 patent was an act of infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

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

167. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

168. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '021 patent.

169. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '021 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

170. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 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 '021 patent after approval of Accord's NDA.

171. The foregoing actions by Accord 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.

172. On information and belief, Accord 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.

173. Unless Accord 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 XII – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 9,579,384 UNDER 35 U.S.C. § 271(e)(2)**

174. Plaintiffs incorporate each of the preceding paragraphs 1–173 as if fully set forth herein.

175. Accord's submission of Accord's NDA 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 '384 patent was an act of infringement of the '384 patent under 35 U.S.C. § 271(e)(2)(A).

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

177. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

178. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '384 patent.

179. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '384 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

180. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 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 '384 patent after approval of Accord's NDA.

181. The foregoing actions by Accord 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.

182. On information and belief, Accord 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.

183. Unless Accord 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 XIII – INFRINGEMENT BY ACCORD
OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)**

184. Plaintiffs incorporate each of the preceding paragraphs 1–183 as if fully set forth herein.

185. Accord's submission of Accord's NDA 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 '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A).

186. On 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 '533 patent, either literally or under the doctrine of equivalents.

187. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

188. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '533 patent.

189. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '533 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

190. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 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 '533 patent after approval of Accord's NDA.

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

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

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

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

194. Plaintiffs incorporate each of the preceding paragraphs 1–193 as if fully set forth herein.

195. Accord's submission of Accord's NDA 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 '385 patent was an act of infringement of the '385 patent under 35 U.S.C. § 271(e)(2)(A).

196. On 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 '385 patent, either literally or under the doctrine of equivalents.

197. On information and belief, Accord will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's NDA Product immediately and imminently upon FDA approval of Accord's NDA.

198. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '385 patent.

199. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '385 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

200. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '385 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 '385 patent after approval of Accord's NDA.

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

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

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

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

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

205. Accord has knowledge of the '707 patent.

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

207. On 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 Accord's NDA.

208. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '707 patent.

209. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '707 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

210. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 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 '707 patent after approval of Accord's NDA.

211. The foregoing actions by Accord 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. On information and belief, Accord 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 Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA 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 Accord's NDA 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. Accord 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
BY ACCORD 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. Accord has knowledge of the '831 patent.

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

219. On 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 Accord's NDA.

220. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '831 patent.

221. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '831 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

222. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 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 '831 patent after approval of Accord's NDA.

223. The foregoing actions by Accord 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.

224. On information and belief, Accord 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.

225. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '831 patent and whether one or more claims of the '831 patent are valid.

226. Plaintiffs 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 '831 patent and that the claims of the '831 patent are valid.

227. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,572,796**

228. Plaintiffs incorporate each of the preceding paragraphs 1–227 as if fully set forth herein.

229. Accord has knowledge of the '796 patent.

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

231. On 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 Accord's NDA.

232. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '796 patent.

233. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '796 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

234. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 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 '796 patent after approval of Accord's NDA.

235. The foregoing actions by Accord 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.

236. On information and belief, Accord 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.

237. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '796 patent and whether one or more claims of the '796 patent are valid.

238. Plaintiffs 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 '796 patent and that the claims of the '796 patent are valid.

239. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,572,797**

240. Plaintiffs incorporate each of the preceding paragraphs 1–239 as if fully set forth herein.

241. Accord has knowledge of the '797 patent.

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

243. On 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 Accord's NDA.

244. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '797 patent.

245. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '797 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

246. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 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 '797 patent after approval of Accord's NDA.

247. The foregoing actions by Accord 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.

248. On information and belief, Accord 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.

249. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '797 patent and whether one or more claims of the '797 patent are valid.

250. Plaintiffs 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 '797 patent and that the claims of the '797 patent are valid.

251. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,034,908**

252. Plaintiffs incorporate each of the preceding paragraphs 1–251 as if fully set forth herein.

253. Accord has knowledge of the '908 patent.

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

255. On 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 Accord's NDA.

256. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '908 patent.

257. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '908 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

258. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 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 '908 patent after approval of Accord's NDA.

259. The foregoing actions by Accord 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.

260. On information and belief, Accord 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.

261. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '908 patent and whether one or more claims of the '908 patent are valid.

262. Plaintiffs 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 '908 patent and that the claims of the '908 patent are valid.

263. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,144,568**

264. Plaintiffs incorporate each of the preceding paragraphs 1–263 as if fully set forth herein.

265. Accord has knowledge of the '568 patent.

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

267. On 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 Accord's NDA.

268. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '568 patent.

269. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '568 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

270. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 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 '568 patent after approval of Accord's NDA.

271. The foregoing actions by Accord 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.

272. On information and belief, Accord 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.

273. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '568 patent and whether one or more claims of the '568 patent are valid.

274. Plaintiffs 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 '568 patent and that the claims of the '568 patent are valid.

275. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,572,887**

276. Plaintiffs incorporate each of the preceding paragraphs 1–275 as if fully set forth herein.

277. Accord has knowledge of the '887 patent.

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

279. On 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 Accord's NDA.

280. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '887 patent.

281. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '887 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

282. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 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 '887 patent after approval of Accord's NDA.

283. The foregoing actions by Accord 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.

284. On information and belief, Accord 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.

285. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

286. Plaintiffs 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 '887 patent and that the claims of the '887 patent are valid.

287. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,597,397**

288. Plaintiffs incorporate each of the preceding paragraphs 1–287 as if fully set forth herein.

289. Accord has knowledge of the '397 patent.

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

291. On 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 Accord's NDA.

292. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '397 patent.

293. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '397 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

294. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 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 '397 patent after approval of Accord's NDA.

295. The foregoing actions by Accord 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.

296. On information and belief, Accord 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.

297. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according

to Accord's NDA will infringe one or more claims of the '397 patent and whether one or more claims of the '397 patent are valid.

298. Plaintiffs 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 '397 patent and that the claims of the '397 patent are valid.

299. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,597,398**

300. Plaintiffs incorporate each of the preceding paragraphs 1–299 as if fully set forth herein.

301. Accord has knowledge of the '398 patent.

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

303. On 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 Accord's NDA.

304. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '398 patent.

305. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '398 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

306. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 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 '398 patent after approval of Accord's NDA.

307. The foregoing actions by Accord 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.

308. On information and belief, Accord 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.

309. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '398 patent and whether one or more claims of the '398 patent are valid.

310. Plaintiffs 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 '398 patent and that the claims of the '398 patent are valid.

311. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,597,399**

312. Plaintiffs incorporate each of the preceding paragraphs 1–311 as if fully set forth herein.

313. Accord has knowledge of the '399 patent.

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

315. On 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 Accord's NDA.

316. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '399 patent.

317. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '399 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

318. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 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 '399 patent after approval of Accord's NDA.

319. The foregoing actions by Accord 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.

320. On information and belief, Accord 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.

321. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '399 patent and whether one or more claims of the '399 patent are valid.

322. Plaintiffs 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 '399 patent and that the claims of the '399 patent are valid.

323. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,000,021**

324. Plaintiffs incorporate each of the preceding paragraphs 1–323 as if fully set forth herein.

325. Accord has knowledge of the '021 patent.

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

327. On 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 Accord's NDA.

328. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '021 patent.

329. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '021 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

330. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 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 '021 patent after approval of Accord's NDA.

331. The foregoing actions by Accord 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.

332. On information and belief, Accord 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.

333. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '021 patent and whether one or more claims of the '021 patent are valid.

334. Plaintiffs 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 '021 patent and that the claims of the '021 patent are valid.

335. Accord 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
BY ACCORD OF U.S. PATENT NO. 9,579,384**

336. Plaintiffs incorporate each of the preceding paragraphs 1–335 as if fully set forth herein.

337. Accord has knowledge of the '384 patent.

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

339. On 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 Accord's NDA.

340. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '384 patent.

341. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '384 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

342. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 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 '384 patent after approval of Accord's NDA.

343. The foregoing actions by Accord 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.

344. On information and belief, Accord 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.

345. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according

to Accord's NDA will infringe one or more claims of the '384 patent and whether one or more claims of the '384 patent are valid.

346. Plaintiffs 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 '384 patent and that the claims of the '384 patent are valid.

347. Accord 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.

**COUNT XXVII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY ACCORD OF U.S. PATENT NO. 10,010,533**

348. Plaintiffs incorporate each of the preceding paragraphs 1–347 as if fully set forth herein.

349. Accord has knowledge of the '533 patent.

350. On 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 '533 patent, either literally or under the doctrine of equivalents.

351. On 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 Accord's NDA.

352. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '533 patent.

353. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '533 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

354. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 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 '533 patent after approval of Accord's NDA.

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

356. On information and belief, Accord has acted without a reasonable basis for believing that it would not be liable for infringing the '533 patent, actively inducing infringement of the '533 patent, and contributing to the infringement by others of the '533 patent.

357. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '533 patent and whether one or more claims of the '533 patent are valid.

358. Plaintiffs 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 '533 patent and that the claims of the '533 patent are valid.

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

**COUNT XXVIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY ACCORD OF U.S. PATENT NO. 10,052,385**

360. Plaintiffs incorporate each of the preceding paragraphs 1–359 as if fully set forth herein.

361. Accord has knowledge of the '385 patent.

362. On 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 '385 patent, either literally or under the doctrine of equivalents.

363. On 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 Accord's NDA.

364. On information and belief, the use of Accord's NDA Product in accordance with and as directed by Accord proposed labeling for that product would infringe one or more claims of the '385 patent.

365. On information and belief, Accord plans and intends to, and will, actively induce infringement of the '385 patent when Accord's NDA is approved, and plans and intends to, and will, do so after approval.

366. On information and belief, Accord knows that Accord's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 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 '385 patent after approval of Accord's NDA.

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

368. On information and belief, Accord has acted without a reasonable basis for believing that it would not be liable for infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent.

369. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Accord regarding whether Accord manufacture, use, sale, offer for sale, or importation into the United States of Accord's NDA Product with its proposed labeling according to Accord's NDA will infringe one or more claims of the '385 patent and whether one or more claims of the '385 patent are valid.

370. Plaintiffs 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 '385 patent and that the claims of the '385 patent are valid.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Accord has infringed, will infringe, and will induce and contribute to infringement of the '707, '831, '796, '797, '908, '568, '887, '397, '398, '399, '021, '384, '533, and '385 patents (the "Patents-in-Suit").

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

(c) A judgment pursuant to, among other things, 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, shall not be 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, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 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 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 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 Plaintiffs' damages or other monetary relief to compensate Plaintiffs 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 Plaintiffs' costs and expenses in this action; and

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

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