IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON LLC, EAGLE PHARMACEUTICALS, INC., and EAGLE SUB1 LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
	)	**ANDA CASE**
ALMAJECT, INC., and ALVOGEN, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon LLC ("Cephalon") (collectively, with Teva Pharmaceuticals, "Teva"), Eagle Pharmaceuticals, Inc. and Eagle Sub1 LLC (collectively, "Eagle") (Teva and 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 Almaject Inc. ("Almaject") and Alvogen, Inc.'s ("Alvogen") (collectively, with Almaject, "Defendants") submission of New Drug Application ("NDA") No. 220186 ("Almaject's NDA") 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"), 10,052,385 (the "'385 patent"), 11,844,783 (the "'783 patent"), 11,872,214 (the "'214 patent"), 12,138,248 (the "'248 patent"), 12,350,257 (the "'257 patent"), and 12,343,333 (the "'333 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 limited liability company 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 Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

5. Plaintiff Eagle Sub1 LLC is a limited liability company organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. Eagle Sub1 LLC is a wholly owned subsidiary of Eagle Pharmaceuticals, Inc.

6. On information and belief, Defendant Almaject is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 44 Whippany Rd. Suite 300, Morristown, NJ 07960. On information and belief, Almaject is in the

business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware. On information and belief, Almaject may be served with process through its registered agent, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

7. On information and belief, Defendant Alvogen is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 44 Whippany Rd. Suite 300, Morristown, NJ 07960. On information and belief, Alvogen is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including Delaware, through various operating subsidiaries, including Almaject. On information and belief, Alvogen may be served with process through its registered agent, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

8. On information and belief, Almaject is a wholly owned subsidiary of Alvogen.

9. On information and belief, Alvogen and Almaject acted in concert to prepare and submit Almaject's NDA to FDA.

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

11. On information and belief, Alvogen and Almaject know and intend that upon approval of Almaject's NDA, Alvogen and/or Almaject will manufacture Almaject's NDA

Product; and Alvogen and Almaject will directly or indirectly market, sell, and distribute Almaject's NDA Product throughout the United States, including in Delaware. On information and belief, Alvogen and Almaject operate in concert as integrated parts of the same business group, including with respect to Almaject's NDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Alvogen, Inc. and Almaject, Inc. participated, assisted, and cooperated in carrying out the acts complained about herein.

12. On information and belief, following any FDA approval of Almaject's NDA, Alvogen and Almaject will act in concert to distribute and sell Almaject's NDA Product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); and this Court is authorized to grant declaratory-judgment relief under 28 U.S.C. §§ 2201 and 2202.

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

15. This Court has personal jurisdiction over Alvogen 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. Alvogen is incorporated in the State of Delaware. On information and belief, Alvogen is registered as a pharmacy wholesaler under license No. A4-0001942 with the Delaware Division of Professional Regulation. Additionally, on information and belief, Alvogen is in the business of manufacturing, marketing, importing, offering to sell, and selling pharmaceutical drug products, including generic drug products, and

therefore transacts or intends to transact business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. On information and belief, Alvogen directly, or indirectly, develops, manufactures, markets, imports, offers to sell, and sells generic drugs throughout the United States and in this District. On information and belief, Alvogen purposefully has conducted and continues to conduct business in this District, and this District is a likely destination of Defendants' generic products.

16. In addition, this Court has personal jurisdiction over Alvogen because, on information and belief, Alvogen directs and controls Almaject. Therefore, Almaject activities in Delaware are attributable to Alvogen.

17. This Court has personal jurisdiction over Almaject 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. Almaject is incorporated in the State of Delaware. Additionally, on information and belief, Almaject is in the business of manufacturing, marketing, importing, offering to sell, and selling pharmaceutical drug products, including generic drug products, and therefore transacts or intends to transact business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. On information and belief, Almaject directly, or indirectly, develops, manufactures, markets, imports, offers to sell, and sells generic drugs throughout the United States and in this District. On information and belief, Almaject purposefully has conducted and continues to conduct business in this District, and this District is a likely destination of Defendants' generic products.

18. In addition, this Court has personal jurisdiction over Almaject because, on information and belief, Alvogen directs and controls Almaject. Therefore, Alvogen's activities in Delaware are attributable to Almaject. In addition, this Court also has personal jurisdiction over

Alvogen and Almaject because, among other things, on information and belief: (1) Alvogen and Almaject filed Almaject's NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject's NDA Product in the United States, including in Delaware; and (2) upon approval of Almaject's NDA, Alvogen and Almaject will market, distribute, offer for sale, sell, and/or import Almaject's NDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Almaject's NDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Almaject's NDA, Almaject'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.

19. In addition, this Court has personal jurisdiction over Alvogen and Almaject 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, Eagle Pharmaceuticals, Inc., and Eagle Sub1 LLC, all Delaware corporate entities.

20. In addition, this Court has personal jurisdiction over Alvogen and Almaject because they regularly engage in patent litigation concerning NDA or Abbreviated New Drug Application ("ANDA") Products in this District, do not contest personal jurisdiction in this District, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District.[1]

[1] *See, e.g.*, *Novo Nordisk Inc. et al. v. Alvogen, Inc.*, C.A. No. 22-299-CFC (D. Del.);

21. For the above reasons, it would not be fundamentally unfair or unreasonable for Alvogen and Almaject to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Alvogen, at least because, on information and belief, Alvogen is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this District.

24. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Almaject, at least because, on information and belief, Almaject is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this District.

25. In addition, Alvogen and Almaject regularly engage in patent litigation concerning Almaject's NDA or ANDA Products in this District and do not contest venue in this District.[2]

BACKGROUND

BioDelivery Scis. Int'l, Inc. v. Alvogen PB Rsch. & Dev. LLC, C.A. No. 18-1395-CFC (D. Del.); *Noven Pharms., Inc. v. Alvogen Pine Brook LLC*, C.A. No. 17-1429-LPS (D. Del.); *Pharmacyclics LLC v. Alvogen Pine Brook LLC*, C.A. No. 19-434-CFC (D. Del.); *Otsuka Pharm. Co. v. Alvogen, Inc. & Almaject, Inc.*, C.A. No. 25-188-JLH (D. Del.).

[2] *See supra* n.1.

26. 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.

27. Eagle Pharmaceuticals, Inc. is the holder of NDA No. 208194 for Bendeka®, which has been approved by FDA.

28. The '707 patent, entitled "Formulations of Bendamustine" (Exhibit A), was duly and legally issued on December 17, 2013. Eagle 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.

29. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit B), was duly and legally issued on February 23, 2016. Eagle 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.

30. The '796 patent, entitled "Formulations of Bendamustine" (Exhibit C), was duly and legally issued on February 21, 2017. Eagle 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.

31. The '797 patent, entitled "Formulations of Bendamustine" (Exhibit D), was duly and legally issued on February 21, 2017. Eagle 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.

32. The ’908 patent, entitled “Formulations of Bendamustine” (Exhibit E), was duly and legally issued on May 19, 2015. Eagle 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.

33. The ’568 patent, entitled “Formulations of Bendamustine” (Exhibit F), was duly and legally issued on September 29, 2015. Eagle 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.

34. The ’887 patent, entitled “Formulations of Bendamustine” (Exhibit G), was duly and legally issued on February 21, 2017. Eagle 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.

35. The ’397 patent, entitled “Formulations of Bendamustine” (Exhibit H), was duly and legally issued on March 21, 2017. Eagle 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.

36. The ’398 patent, entitled “Formulations of Bendamustine” (Exhibit I), was duly and legally issued on March 21, 2017. Eagle 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.

37. The ’399 patent, entitled “Formulations of Bendamustine” (Exhibit J), was duly and legally issued on March 21, 2017. Eagle 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.

38. 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 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.

39. 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 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.

40. The '533 patent, entitled "Formulations of Bendamustine" (Exhibit M), was duly and legally issued on July 3, 2018. Eagle 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.

41. The '385 patent, entitled "Formulations of Bendamustine" (Exhibit N), was duly and legally issued on August 21, 2018. Eagle 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.

42. The '783 patent, entitled "Formulations of Bendamustine" (Exhibit O), was duly and legally issued on December 19, 2023. Eagle is the owner and assignee of the '783 patent,

subject to the exclusive license referenced herein. The '783 patent has been listed in connection with Bendeka® in the Orange Book.

43. The '214 patent, entitled "Formulations of Bendamustine" (Exhibit P), was duly and legally issued on January 16, 2024. Eagle is the owner and assignee of the '214 patent, subject to the exclusive license referenced herein. The '214 patent has been listed in connection with Bendeka® in the Orange Book.

44. The '248 patent, entitled "Formulations of Bendamustine" (Exhibit Q), was duly and legally issued on November 12, 2024. Eagle is the owner and assignee of the '248 patent, subject to the exclusive license referenced herein. The '248 patent has been listed in connection with Bendeka® in the Orange Book.

45. The '257 patent, entitled "Formulations of Bendamustine" (Exhibit R), was duly and legally issued on July 8, 2025. Eagle is the owner and assignee of the '257 patent, subject to the exclusive license referenced herein. The '257 patent has been listed in connection with Bendeka® in the Orange Book.

46. The '333 patent, entitled "Formulations of Bendamustine" (Exhibit S), was duly and legally issued on July 1, 2025. Eagle is the owner and assignee of the '333 patent, subject to the exclusive license referenced herein.

47. 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, '385, '783, '214,'248, '257, and

'333 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.

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

INFRINGEMENT BY DEFENDANTS

49. By letter dated August 6, 2025 ("Almaject's Notice Letter"), Almaject, as wholly owned subsidiary of Alvogen, notified Teva and Eagle that it had filed a Paragraph IV Certification with respect to the '707, '831, '796, '797, '908 '568, '887, '397, '398, '399, '021, '384, '533, '385, '783, '214, and '248 patents (the "Notice Letter Patents"), among others, and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject's NDA Product prior to the expiration of the Notice Letter Patents. On information and belief, Almaject's NDA contains a Paragraph IV Certification asserting that the Notice Letter Patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Almaject's NDA Product, or alternatively, that the Notice Letter Patents are invalid.

50. The purpose of Defendants' submission of Almaject'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 Almaject's NDA Product prior to the expiration of the Patents-in-Suit, including the Notice Letter Patents.

51. In Almaject's Notice Letter, Defendants stated that the active ingredient of Almaject's NDA Product is bendamustine hydrochloride.

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

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

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

55. On information and belief, Almaject'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, Almaject's NDA Product contains bendamustine, polyethylene glycol, and optionally one or more of propylene glycol, ethanol, benzyl alcohol, and glycofurol.

57. On information and belief, Almaject's NDA Product contains a stabilizing amount of an antioxidant.

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

59. On information and belief, the proposed labeling for Almaject's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m^2 to patients with chronic lymphocytic leukemia.

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

61. On information and belief, Almaject's NDA Product has less than or equal to 0.11% total PG esters at about 1 month of storage at a temperature of about 5 °C.

62. On information and belief, Almaject's NDA Product has less than about 5% total impurities as determined by HPLC at a wavelength of 223 nm after 15 months at a temperature of from about 5 °C. to about 25 °C.

63. On information and belief, Almaject's NDA Product has less than about 5% total impurities after 15 months of storage at about 5 °C., as calculated on a normalized peak area response basis as determined by high performance liquid chromatography at a wavelength of 223 nm.

64. On information and belief, Almaject's NDA Product has less than about 5% peak area response of total impurities, as measured by HPLC, resulting from the degradation of bendamustine after being stored at a temperature between about 5 °C to 25 °C for fifteen months.

65. On information and belief, the proposed labeling for Almaject's NDA Product recommends, encourages, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m^2 to patients with indolent B-cell non-Hodgkin lymphoma.

66. On information and belief, the proposed labeling for Almaject's NDA Product recommends, encourages, instructs, and/or promotes the dilution of Almaject's NDA Product into a pharmaceutically acceptable diluent.

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

68. On information and belief, Almaject's NDA Product is supplied in a sterile vial.

69. In an exchange of correspondence, counsel for Teva and counsel for Almaject discussed the terms of Almaject's Offer for Confidential Access. The parties did not agree on terms under which Teva could review, among other things, Almaject's NDA and certain Drug Master Files referred to therein, and Almaject refused to produce samples of Almaject's NDA Product and other internal documents and materials relevant to infringement. In addition, the Offer for Confidential Access placed unreasonable restrictions on the extent to which Teva and its consultants could access the documents and materials subject to the offer. Without all of the materials requested by Teva, including samples of Almaject's NDA Product, which Almaject refused to produce, Teva could not confirm, and cannot confirm, the exact composition and properties of Almaject's NDA Product. Defendants filing of Almaject's NDA seeking approval to market a generic version of Bendeka® before expiry of the patents asserted herein constitutes an act of infringement.

70. On September 15, 2025, shortly before forty-five days had elapsed following Plaintiffs' receipt of Almaject's Notice Letter, counsel for Almaject responded to Teva's then-most-recent correspondence regarding Almaject's Offer for Confidential Access and maintained both its refusal to provide the full scope of materials and information requested by Teva and its refusal to allow access to its confidential information on reasonable terms. On

September 16, 2025, counsel for Teva responded by letter recognizing that the parties were at an impasse.

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

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

72. Plaintiffs incorporate each of the preceding paragraphs 1–71 as if fully set forth herein.

73. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

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

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

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

77. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '707 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

78. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '707 patent after approval of Almaject's NDA.

79. The foregoing actions by Defendants 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.

80. On information and belief, Defendants have acted with full knowledge of the '707 patent and without a reasonable basis for believing that they 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.

81. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)

82. Plaintiffs incorporate each of the preceding paragraphs 1–81 as if fully set forth herein.

83. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

84. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

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

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

87. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '831 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

88. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '831 patent after approval of Almaject's NDA.

89. The foregoing actions by Defendants 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.

90. On information and belief, Defendants have acted with full knowledge of the '831 patent and without a reasonable basis for believing that they 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.

91. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)

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

93. Defendants’ submission of Almaject’s NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject’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).

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

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

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

97. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '796 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

98. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '796 patent after approval of Almaject's NDA.

99. The foregoing actions by Defendants 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.

100. On information and belief, Defendants have acted with full knowledge of the '796 patent and without a reasonable basis for believing that they 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.

101. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)

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

103. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

104. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

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

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

107. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '797 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

108. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '797 patent after approval of Almaject's NDA.

109. The foregoing actions by Defendants 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.

110. On information and belief, Defendants have acted with full knowledge of the '797 patent and without a reasonable basis for believing that they 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.

111. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,034,908 UNDER 35 U.S.C. § 271(e)(2)

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

113. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

114. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

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

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

117. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '908 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

118. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '908 patent after approval of Almaject's NDA.

119. The foregoing actions by Defendants 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.

120. On information and belief, Defendants have acted with full knowledge of the '908 patent and without a reasonable basis for believing that they 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.

121. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 9,144,568 UNDER 35 U.S.C. § 271(e)(2)

122. Plaintiffs incorporate each of the preceding paragraphs 1–121 as if fully set forth herein.

123. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

124. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '568 patent, either literally or under the doctrine of equivalents.

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

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

127. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '568 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

128. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '568 patent after approval of Almaject's NDA.

129. The foregoing actions by Defendants 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.

130. On information and belief, Defendants have acted with full knowledge of the '568 patent and without a reasonable basis for believing that they 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.

131. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)

132. Plaintiffs incorporate each of the preceding paragraphs 1–131 as if fully set forth herein.

133. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

134. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

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

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

137. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '887 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

138. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '887 patent after approval of Almaject's NDA.

139. The foregoing actions by Defendants 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.

140. On information and belief, Defendants have acted with full knowledge of the '887 patent and without a reasonable basis for believing that they 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.

141. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 9,597,397 UNDER 35 U.S.C. § 271(e)(2)

142. Plaintiffs incorporate each of the preceding paragraphs 1–141 as if fully set forth herein.

143. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

144. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '397 patent, either literally or under the doctrine of equivalents.

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

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

147. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '397 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

148. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '397 patent after approval of Almaject's NDA.

149. The foregoing actions by Defendants 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.

150. On information and belief, Defendants have acted with full knowledge of the '397 patent and without a reasonable basis for believing that they 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.

151. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,597,398 UNDER 35 U.S.C. § 271(e)(2)

152. Plaintiffs incorporate each of the preceding paragraphs 1–151 as if fully set forth herein.

153. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

154. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

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

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

157. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '398 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

158. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '398 patent after approval of Almaject's NDA.

159. The foregoing actions by Defendants 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.

160. On information and belief, Defendants have acted with full knowledge of the '398 patent and without a reasonable basis for believing that they 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.

161. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 9,597,399 UNDER 35 U.S.C. § 271(e)(2)

162. Plaintiffs incorporate each of the preceding paragraphs 1–161 as if fully set forth herein.

163. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

164. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '399 patent, either literally or under the doctrine of equivalents.

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

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

167. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '399 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

168. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '399 patent after approval of Almaject's NDA.

169. The foregoing actions by Defendants 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.

170. On information and belief, Defendants have acted with full knowledge of the ’399 patent and without a reasonable basis for believing that they 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.

171. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 9,000,021 UNDER 35 U.S.C. § 271(e)(2)

172. Plaintiffs incorporate each of the preceding paragraphs 1–171 as if fully set forth herein.

173. Defendants’ submission of Almaject’s NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject’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).

174. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’021 patent, either literally or under the doctrine of equivalents.

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

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

177. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '021 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

178. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '021 patent after approval of Almaject's NDA.

179. The foregoing actions by Defendants 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.

180. On information and belief, Defendants have acted with full knowledge of the '021 patent and without a reasonable basis for believing that they 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.

181. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 9,579,384 UNDER 35 U.S.C. § 271(e)(2)

182. Plaintiffs incorporate each of the preceding paragraphs 1–181 as if fully set forth herein.

183. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

184. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '384 patent, either literally or under the doctrine of equivalents.

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

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

187. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '384 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

188. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '384 patent after approval of Almaject's NDA.

189. The foregoing actions by Defendants 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.

190. On information and belief, Defendants have acted with full knowledge of the '384 patent and without a reasonable basis for believing that they 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.

191. Unless Defendants are 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 DEFENDANTS OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)

192. Plaintiffs incorporate each of the preceding paragraphs 1–191 as if fully set forth herein.

193. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject'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).

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

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

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

197. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '533 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

198. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '533 patent after approval of Almaject's NDA.

199. The foregoing actions by Defendants 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.

200. On information and belief, Defendants have acted with full knowledge of the '533 patent and without a reasonable basis for believing that they 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.

201. Unless Defendants are 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 DEFENDANTS
OF U.S. PATENT NO. 10,052,385 UNDER 35 U.S.C. § 271(e)(2)

202. Plaintiffs incorporate each of the preceding paragraphs 1–201 as if fully set forth herein.

203. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject'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).

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

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

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

207. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '385 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

208. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '385 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '385 patent after approval of Almaject's NDA.

209. The foregoing actions by Defendants 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.

210. On information and belief, Defendants have acted with full knowledge of the '385 patent and without a reasonable basis for believing that they 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.

211. Unless Defendants are 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 – INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 11,844,783 UNDER 35 U.S.C. § 271(e)(2)

212. Plaintiffs incorporate each of the preceding paragraphs 1–211 as if fully set forth herein.

213. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject's NDA Product prior to the expiration of the '783 patent was an act of infringement of the '783 patent under 35 U.S.C. § 271(e)(2)(A).

214. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '783 patent, either literally or under the doctrine of equivalents.

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

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

217. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '783 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

218. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '783 patent after approval of Almaject's NDA.

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

220. On information and belief, Defendants have acted with full knowledge of the '783 patent and without a reasonable basis for believing that they would not be liable for infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent.

221. Unless Defendants are enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVI – INFRINGEMENT BY DEFENDANTS
OF U.S. PATENT NO. 11,872,214 UNDER 35 U.S.C. § 271(e)(2)

222. Plaintiffs incorporate each of the preceding paragraphs 1–221 as if fully set forth herein.

223. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject's NDA Product prior to the expiration of the '214 patent was an act of infringement of the '214 patent under 35 U.S.C. § 271(e)(2)(A).

224. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '214 patent, either literally or under the doctrine of equivalents.

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

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

227. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '214 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

228. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '214 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '214 patent after approval of Almaject's NDA.

229. The foregoing actions by Defendants constitute and/or will constitute infringement of the '214 patent, active inducement of infringement of the '214 patent, and contribution to the infringement by others of the '214 patent.

230. On information and belief, Defendants have acted with full knowledge of the '214 patent and without a reasonable basis for believing that they would not be liable for infringing the '214 patent, actively inducing infringement of the '214 patent, and contributing to the infringement by others of the '214 patent.

231. Unless Defendants are enjoined from infringing the '214 patent, actively inducing infringement of the '214 patent, and contributing to the infringement by others of the '214 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVII – INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 12,138,248 UNDER 35 U.S.C. § 271(e)(2)

232. Plaintiffs incorporate each of the preceding paragraphs 1–232 as if fully set forth herein.

233. Defendants' submission of Almaject's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Almaject's NDA Product prior to the expiration of the '248 patent was an act of infringement of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

234. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '248 patent, either literally or under the doctrine of equivalents.

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

236. On information and belief, the use of Almaject's NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '248 patent.

237. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’248 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

238. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’248 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’248 patent after approval of Almaject’s NDA.

239. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’248 patent, active inducement of infringement of the ’248 patent, and contribution to the infringement by others of the ’248 patent.

240. On information and belief, Defendants have acted with full knowledge of the ’248 patent and without a reasonable basis for believing that they would not be liable for infringing the ’248 patent, actively inducing infringement of the ’248 patent, and contributing to the infringement by others of the ’248 patent.

241. Unless Defendants are enjoined from infringing the ’248 patent, actively inducing infringement of the ’248 patent, and contributing to the infringement by others of the ’248 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVIII – INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 12,350,257 UNDER 35 U.S.C. § 271(e)(2)

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

243. Defendants’ submission of Almaject’s NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Almaject's NDA Product prior to the expiration of the '257 patent was an act of infringement of the '257 patent under 35 U.S.C. § 271(e)(2)(A).

244. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '257 patent, either literally or under the doctrine of equivalents.

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

246. On information and belief, the use of Almaject's NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '257 patent.

247. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '257 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

248. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '257 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '257 patent after approval of Almaject's NDA.

249. The foregoing actions by Defendants constitute and/or will constitute infringement of the '257 patent, active inducement of infringement of the '257 patent, and contribution to the infringement by others of the '257 patent.

250. On information and belief, Defendants have acted with full knowledge of the ’257 patent and without a reasonable basis for believing that they would not be liable for infringing the ’257 patent, actively inducing infringement of the ’257 patent, and contributing to the infringement by others of the ’257 patent.

251. Unless Defendants are enjoined from infringing the ’257 patent, actively inducing infringement of the ’257 patent, and contributing to the infringement by others of the ’257 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIX – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 8,609,707

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

253. Defendants have knowledge of the ’707 patent.

254. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’707 patent, either literally or under the doctrine of equivalents.

255. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

257. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’707 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

258. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '707 patent after approval of Almaject's NDA.

259. The foregoing actions by Defendants 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.

260. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

261. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Almaject's NDA Product with its proposed labeling according to Almaject's NDA will infringe one or more claims of the '707 patent and whether one or more claims of the '707 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 Almaject'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.

263. Defendants 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 XX – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,265,831

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

265. Defendants have knowledge of the '831 patent.

266. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

267. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

269. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '831 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

270. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '831 patent after approval of Almaject's NDA.

271. The foregoing actions by Defendants 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.

272. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

275. Defendants 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 XXI – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,572,796

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

277. Defendants have knowledge of the ’796 patent.

278. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

279. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

281. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '796 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

282. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '796 patent after approval of Almaject's NDA.

283. The foregoing actions by Defendants 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.

284. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

287. Defendants 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 XXII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,572,797

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

289. Defendants have knowledge of the '797 patent.

290. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

291. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

293. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '797 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

294. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '797 patent after approval of Almaject's NDA.

295. The foregoing actions by Defendants 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.

296. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

299. Defendants 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 XXIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,034,908

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

301. Defendants have knowledge of the '908 patent.

302. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

303. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

305. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '908 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

306. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '908 patent after approval of Almaject's NDA.

307. The foregoing actions by Defendants 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.

308. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

311. Defendants 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 XXIV – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,144,568

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

313. Defendants have knowledge of the ’568 patent.

314. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’568 patent, either literally or under the doctrine of equivalents.

315. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

317. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’568 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

318. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’568 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '568 patent after approval of Almaject's NDA.

319. The foregoing actions by Defendants 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.

320. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

323. Defendants 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 XXV – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,572,887

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

325. Defendants have knowledge of the ’887 patent.

326. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’887 patent, either literally or under the doctrine of equivalents.

327. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

329. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’887 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

330. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’887 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’887 patent after approval of Almaject’s NDA.

331. The foregoing actions by Defendants 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.

332. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

335. Defendants 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 XXVI – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,597,397

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

337. Defendants have knowledge of the ’397 patent.

338. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’397 patent, either literally or under the doctrine of equivalents.

339. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

341. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '397 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

342. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '397 patent after approval of Almaject's NDA.

343. The foregoing actions by Defendants 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.

344. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

according to Almaject's NDA will infringe one or more claims of the '397 patent and whether one or more claims of the '397 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 Almaject'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.

347. Defendants 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 XXVII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,597,398

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

349. Defendants have knowledge of the '398 patent.

350. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

351. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

353. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '398 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

354. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '398 patent after approval of Almaject's NDA.

355. The foregoing actions by Defendants 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.

356. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

359. Defendants 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 XXVIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,597,399

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

361. Defendants have knowledge of the ’399 patent.

362. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’399 patent, either literally or under the doctrine of equivalents.

363. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

365. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’399 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

366. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’399 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '399 patent after approval of Almaject's NDA.

367. The foregoing actions by Defendants 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.

368. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

371. Defendants 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 XXIX – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,000,021

372. Plaintiffs incorporate each of the preceding paragraphs 1–371 as if fully set forth herein.

373. Defendants have knowledge of the ’021 patent.

374. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’021 patent, either literally or under the doctrine of equivalents.

375. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

377. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’021 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

378. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’021 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’021 patent after approval of Almaject’s NDA.

379. The foregoing actions by Defendants 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.

380. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

382. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject’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.

383. Defendants 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 XXX – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,579,384

384. Plaintiffs incorporate each of the preceding paragraphs 1–383 as if fully set forth herein.

385. Defendants have knowledge of the ’384 patent.

386. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’384 patent, either literally or under the doctrine of equivalents.

387. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

389. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '384 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

390. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '384 patent after approval of Almaject's NDA.

391. The foregoing actions by Defendants 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.

392. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

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

394. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject'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.

395. Defendants 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 XXXI – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 10,010,533

396. Plaintiffs incorporate each of the preceding paragraphs 1–395 as if fully set forth herein.

397. Defendants have knowledge of the '533 patent.

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

399. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

401. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '533 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

402. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '533 patent after approval of Almaject's NDA.

403. The foregoing actions by Defendants 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.

404. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

406. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject'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.

407. Defendants 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 XXXII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 10,052,385

408. Plaintiffs incorporate each of the preceding paragraphs 1–407 as if fully set forth herein.

409. Defendants have knowledge of the ’385 patent.

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

411. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

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

413. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’385 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

414. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’533 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '385 patent after approval of Almaject's NDA.

415. The foregoing actions by Defendants 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.

416. On information and belief, Defendants have acted without a reasonable basis for believing that they 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.

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

418. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject'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.

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

COUNT XXXIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 11,844,783

420. Plaintiffs incorporate each of the preceding paragraphs 1–419 as if fully set forth herein.

421. Defendants have knowledge of the '783 patent.

422. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '783 patent, either literally or under the doctrine of equivalents.

423. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

425. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '783 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

426. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '783 patent after approval of Almaject's NDA.

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

428. On information and belief, Defendants have acted without a reasonable basis for believing that they would not be liable for infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent.

429. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Almaject's NDA Product with its proposed labeling according to Almaject's NDA will infringe one or more claims of the '783 patent and whether one or more claims of the '783 patent are valid.

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

431. Defendants should be enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXXIV – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 11,872,214

432. Plaintiffs incorporate each of the preceding paragraphs 1–431 as if fully set forth herein.

433. Defendants have knowledge of the '214 patent.

434. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '214 patent, either literally or under the doctrine of equivalents.

435. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

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

437. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '214 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

438. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '214 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '214 patent after approval of Almaject's NDA.

439. The foregoing actions by Defendants constitute and/or will constitute infringement of the '214 patent, active inducement of infringement of the '214 patent, and contribution to the infringement by others of the '214 patent.

440. On information and belief, Defendants have acted without a reasonable basis for believing that they would not be liable for infringing the '214 patent, actively inducing infringement of the '214 patent, and contributing to the infringement by others of the '214 patent.

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

according to Almaject's NDA will infringe one or more claims of the '214 patent and whether one or more claims of the '214 patent are valid.

442. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '214 patent and that the claims of the '214 patent are valid.

443. Defendants should be enjoined from infringing the '214 patent, actively inducing infringement of the '214 patent, and contributing to the infringement by others of the '214 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXXV – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 12,138,248

444. Plaintiffs incorporate each of the preceding paragraphs 1–443 as if fully set forth herein.

445. Defendants have knowledge of the '248 patent.

446. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product would infringe one or more claims of the '248 patent, either literally or under the doctrine of equivalents.

447. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject's NDA Product with its proposed labeling upon FDA approval of Almaject's NDA.

448. On information and belief, the use of Almaject's NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '248 patent.

449. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '248 patent when Almaject's NDA is approved, and plans and intends to, and will, do so after approval.

450. On information and belief, Defendants know that Almaject's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '248 patent and that Almaject's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '248 patent after approval of Almaject's NDA.

451. The foregoing actions by Defendants constitute and/or will constitute infringement of the '248 patent, active inducement of infringement of the '248 patent, and contribution to the infringement by others of the '248 patent.

452. On information and belief, Defendants have acted without a reasonable basis for believing that they would not be liable for infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent.

453. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Almaject's NDA Product with its proposed labeling according to Almaject's NDA will infringe one or more claims of the '248 patent and whether one or more claims of the '248 patent are valid.

454. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '248 patent and that the claims of the '248 patent are valid.

455. Defendants should be enjoined from infringing the ’248 patent, actively inducing infringement of the ’248 patent, and contributing to the infringement by others of the ’248 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXXVI – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 12,350,257

456. Plaintiffs incorporate each of the preceding paragraphs 1–455 as if fully set forth herein.

457. Defendants have knowledge of the ’257 patent.

458. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’257 patent, either literally or under the doctrine of equivalents.

459. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

460. On information and belief, the use of Almaject’s NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’257 patent.

461. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’257 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

462. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’257 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '257 patent after approval of Almaject's NDA.

463. The foregoing actions by Defendants constitute and/or will constitute infringement of the '257 patent, active inducement of infringement of the '257 patent, and contribution to the infringement by others of the '257 patent.

464. On information and belief, Defendants have acted without a reasonable basis for believing that they would not be liable for infringing the '257 patent, actively inducing infringement of the '257 patent, and contributing to the infringement by others of the '257 patent.

465. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Almaject's NDA Product with its proposed labeling according to Almaject's NDA will infringe one or more claims of the '257 patent and whether one or more claims of the '257 patent are valid.

466. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '257 patent and that the claims of the '257 patent are valid.

467. Defendants should be enjoined from infringing the '257 patent, actively inducing infringement of the '257 patent, and contributing to the infringement by others of the '257 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXXVII – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 12,343,333

468. Plaintiffs incorporate each of the preceding paragraphs 1–467 as if fully set forth herein.

469. Defendants have knowledge of the ’333 patent.

470. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product would infringe one or more claims of the ’333 patent, either literally or under the doctrine of equivalents.

471. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Almaject’s NDA Product with its proposed labeling upon FDA approval of Almaject’s NDA.

472. On information and belief, the use of Almaject’s NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’333 patent.

473. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’333 patent when Almaject’s NDA is approved, and plans and intends to, and will, do so after approval.

474. On information and belief, Defendants know that Almaject’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’333 patent and that Almaject’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’333 patent after approval of Almaject’s NDA.

475. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’333 patent, active inducement of infringement of the ’333 patent, and contribution to the infringement by others of the ’333 patent.

476. On information and belief, Defendants have acted without a reasonable basis for believing that they would not be liable for infringing the ’333 patent, actively inducing infringement of the ’333 patent, and contributing to the infringement by others of the ’333 patent.

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

478. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Almaject’s NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’333 patent and that the claims of the ’333 patent are valid.

479. Defendants should be enjoined from infringing the ’333 patent, actively inducing infringement of the ’333 patent, and contributing to the infringement by others of the ’333 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 Defendants have 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, ’385, ’783, ’214, ’248, ’257, and ’333 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 Defendants to make, use, offer for sale, sell, market, distribute, or import Almaject's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '707, '831, '796, '797, '908 '568, '887, '397, '398, '399, '021, '384, '533, '385, '783, '214, '248, and '257 patents, shall not be earlier than the latest of the expiration dates of the '707, '831, '796, '797, '908 '568, '887, '397, '398, '399, '021, '384, '533, '385, '783, '214, '248, and '257 patents, 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/or 283 enjoining Defendants, their 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 Almaject'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 Almaject'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 Defendants engage in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Almaject'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) and/or 284;

(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.

BAYARD, P.A.

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