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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NEVAKAR INJECTABLES, INC., Plaintiff, v. INFORLIFE SA and WG CRITICAL CARE, LLC, Defendants.	C.A. No. 3:22-cv-6886 **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Nevakar Injectables, Inc. ("Nevakar Injectables"), by and through its undersigned attorneys, for its Complaint against Defendants InfoRLife SA ("InfoRLife") and WG Critical Care, LLC ("WG Critical Care,") (collectively "Defendants"), alleges as follows.

NATURE OF THE ACTION

1. This is an action under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, for patent infringement by Defendants of U.S. Patent Nos. 10,226,436 (the "'436 Patent"), 10,420,735 (the "'735 Patent"),

and 10,568,850 (the "'850 Patent,") (collectively the "patents-in-suit") based upon a real, immediate, substantial, and justiciable controversy between the parties.

2. The acts of infringement relate to Defendants' ongoing and/or imminent manufacture, use, sale, importation, offer to sell and/or encouragement of others to do any of the foregoing, within the United States, of ready-to-administer norepinephrine bitartrate in 0.9% sodium chloride solutions before expiration of the patents-in-suit.

THE PARTIES

3. Nevakar Injectables Inc. ("Nevakar Injectables") is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1019 US Highway 202-206, Building K, NJ Center of Excellence, Bridgewater, New Jersey 08807. Nevakar Injectables maintains an established portfolio of products focused on critical patient care, acute pain management, long acting injectables, and hospital infections. Nevakar Injectables' critical care product portfolio is comprised of ready-to-use products in prefilled syringes and intravenous infusion bags. These novel product presentations with longer shelf-life stability save precious time for critically ill patients and health care providers, ensure safety in handling of potent compounds, and reduce cost burden to hospitals.

4. Nevakar Injectables is the holder of New Drug Application ("NDA") No. 214628 for norepinephrine bitartrate in 0.9% sodium chloride solutions for intravenous administration, which has been approved by the Food and Drug Administration ("FDA").

5. Nevakar Injectables is the owner and assignee of the patents-in-suit, by assignment from Nevakar Injectables' parent company, Nevakar Inc., dated on or about July 30, 2022. Nevakar Inc. applied for and obtained patents related to its inventions for ready-to-administer norepinephrine solutions, including the patents-in-suit.

6. On information and belief, Defendant InfoRLife SA ("InfoRLife") is a company organized and existing under the laws of Switzerland, with its principal place of business at Casai, 7748 Campasico, Switzerland. On information and belief, InfoRLife is a pharmaceutical company that produces ready-to-use medicines in plastic packaging primarily for the United States market. The Company's line of business includes the manufacturing, fabricating, or processing of drugs in pharmaceutical preparations.

7. On information and belief, Defendant InfoRLife has a place of business in care of Interchem Corporation, 120 Route 17 North, Suite 115, Paramus, New Jersey 07652.

8. On information and belief, Defendant WG Critical Care is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652. On information and belief, WG Critical Care is an injectable pharmaceutical company that focuses on providing the hospital and specialty markets with critical care products.

JURISDICTION AND VENUE

9. This action arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

10. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq.*). Jurisdiction is also based on the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based on an actual and continuing controversy between the parties concerning the patents-in-suit as detailed below.

11. This Court has personal jurisdiction over Defendants because Defendants' contacts within this judicial district are continuous and systematic. On information and belief,

InfoRLife and WG Critical Care, individually and collectively acting in concert and cooperatively, develop, manufacture, seek approval for, and sell certain FDA-approved pharmaceutical drugs that are regularly marketed, distributed, and sold in New Jersey and throughout the United States.

12. This Court has personal jurisdiction over InfoRLife because of, *inter alia*, InfoRLife's continuous and systematic contacts with corporate entities within this judicial district, including with WG Critical Care, and InfoRLife's manufacturing, marketing, and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district.

13. This Court has personal jurisdiction over WG Critical Care because it is a limited liability company organized and existing under the laws of the State of New Jersey, has a principal place of business in New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey.

14. On information and belief, Defendants directly or indirectly manufacture, market, and sell drug products throughout the United States and in this judicial district.

15. On information and belief, Defendants purposefully have conducted and continue to conduct business in this judicial district, and this judicial district is a destination of Defendants' pharmaceutical products.

16. On information and belief, InfoRLife and WG Critical Care have previously availed themselves of the jurisdiction of this Court by filing complaints in this judicial district. *See, e.g.*, *InfoRLife SA and WG Critical Care, LLC v. Sun Pharmaceutical Industries et al.*, No. 1:21-cv-01740-CFC (D.N.J.).

17. On information and belief, InfoRLife and WG Critical Care work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this judicial district.

18. This Court also has personal jurisdiction over Defendants because this suit arises out of and relates to their activities that are, and will be, directed to the State of New Jersey. On information and belief, Defendants have, in concert with one another, obtained approval on September 15, 2022 from the FDA for a norepinephrine bitartrate in 0.9% sodium chloride solutions for intravenous administration under NDA No. 215700 (the "Accused Product"), and have commenced and/or will imminently commence manufacturing, marketing, and sale of the Accused Product that is the subject of the infringement claims in this action, in the State of New Jersey and throughout the United States, including in this judicial district.

19. For the product described in NDA No. 215700, Defendants have obtained FDA approval and on information and belief are currently manufacturing or directing and controlling the manufacture of, and/or are actively preparing to manufacture or direct and control the manufacture of, and/or will imminently manufacture or direct and control the imminent manufacture of, the Accused Product for commercial distribution from facilities in New Jersey owned by InfoRLife and/or WG Critical Care.

20. On information and belief, Defendants do substantial business in New Jersey, derive substantial revenue from New Jersey, and engage in other persistent courses of conduct in New Jersey. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Defendants.

21. Venue is proper in this district as to WG Critical Care pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, upon information and belief, WG Critical Care is a limited liability company organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to InfoRLife pursuant to 28 U.S.C. § 1391(c)(3) as it is a foreign corporation and is subject to personal jurisdiction in this district.

NEVAKAR INJECTABLES' PRODUCT AND THE PATENTS-IN-SUIT

23. Nevakar Injectables sells and markets, or intends to sell and market, its norepinephrine bitartrate in 0.9% sodium chloride solution product under NDA No. 214628, which was approved by the FDA on October 6, 2022.

24. Norepinephrine bitartrate injection is indicated to control blood pressure in adult patients with acute hypotension.

25. The '436 Patent, entitled "Norepinephrine Compositions and Methods Therefor," was duly and legally issued on March 12, 2019 by the United States Patent and Trademark Office ("USPTO").

26. Nevakar Injectables is the assignee of the '436 Patent.

27. The '436 Patent stems from U.S. Application No. 15/883,798 ("the '798 Application"), filed on January 30, 2018, which claims priority to U.S. Provisional Application No. 62/452,220, filed January 30, 2017.

28. The '436 Patent claims are directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

29. The '436 Patent is valid and duly issued, and will not expire until at least January 30, 2038.

30. The ’735 Patent, entitled “Norepinephrine Compositions and Methods Therefor,” was duly and legally issued on September 24, 2019 by the USPTO.

31. Nevakar Injectables is the assignee of the ’735 Patent.

32. The ’735 Patent stems from U.S. Application No. 16/163,480 (“the ’480 Application”), filed on October 17, 2018, which claims priority to the ’798 Application.

33. The ’735 Patent claims are directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

34. The ’735 Patent is valid and duly issued, and will not expire until at least January 30, 2038.

35. The ’850 Patent, entitled “Norepinephrine Compositions and Methods Therefor,” was duly and legally issued on February 25, 2020 by the USPTO.

36. Nevakar Injectables is the assignee of the ’850 Patent.

37. The ’850 Patent stems from U.S. Application No. 16/239,461 (“the ’461 Application”), filed on January 3, 2019, which claims priority to the ’798 Application.

38. The ’850 Patent claims are directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

39. The ’850 Patent is valid and duly issued, and will not expire until at least January 30, 2038.

40. A true and correct copy of the patents-in-suit is attached hereto as **Exhibit A**.

THE ACCUSED PRODUCT AND INFRINGING CONDUCT

41. On information and belief, Defendants entered into a development, license, and/or commercialization agreement (“Agreement”) amongst themselves for Defendants to develop,

manufacture, have manufactured, distribute, use, market, have marketed, sell, have sold, import, and/or otherwise commercialize, *inter alia*, the Accused Product.

42. On information and belief, in connection with the Agreement, Defendants have engaged in a coordinated scheme to manufacture and sell the Accused Product.

43. Based upon FDA records, InfoRLife is holder of approved NDA No. 215700, which the FDA approved on or about September 15, 2022.

44. According to the FDA-approved label for NDA No. 215700, as revised in October 2022, the Accused Product is a norepinephrine bitartrate in sodium chloride injection supplied as a sterile aqueous ready-to-use solution in 250 mL single-dose containers in three strengths: 4 mg equivalent of norepinephrine (16 mcg per mL), 8 mg equivalent of norepinephrine (32 mcg per mL), and 16 mg equivalent of norepinephrine (64 mcg per mL). A true and correct copy of the FDA-approved label for NDA No. 215700 is attached hereto as **Exhibit B**. The FDA-approved label lists WG Critical Care as the packager of the Accused Product.

45. Publicly available information, including the FDA-approved product label for the Accused Product, describe the Accused Product, and how it is manufactured. *See generally* **Exhibit B**.

46. Specifically, on information and belief, the Accused Product is a norepinephrine bitartrate in sodium chloride composition presented in a ready to administer product that requires no further dilution prior to infusion. *See generally* Exhibit B. The Accused Product is indicated to raise blood pressure in adult patients with severe, acute hypotension. *Id.* at § 1. It is administered to an individual in need at an initial dosage of 8 to 12 mcg per minute via intravenous infusion, and typical maintenance intravenous dosage is 2 to 4 mcg per minute. *Id.* at § 2.2. It is supplied as a sterile aqueous ready-to-use solution in 250 mL transparent intravenous

bags. *Id.* at § 11. Each mL contains the equivalent of 16, 32 or 64 micrograms of norepinephrine base supplied as 32, 64 or 128 micrograms per mL of norepinephrine bitartrate monohydrate. *Id.* at § 11. It contains sodium chloride (9 mg/mL) and may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. *Id.* at § 11. It has a pH of 3.4 to 4.0. *Id.* at § 11. Each filled bag is packed in an overwrap with a transparent band and oxygen scavenger and oxygen indicator placed inside the overwrapping to prevent deterioration of drug product. *Id.* at § 16.

47. On information and belief, Defendants collaborated in the research, development, preparation, and filing of NDA No. 215700 for the Accused Product, and further collaborated in the plans and preparation for the commercial manufacture of the Accused Product in the United States.

48. Because the Accused Product has been approved by the FDA, Defendants can manufacture, have manufactured, offer for sale, and sell that product commercially in the United States and in this District.

49. On information and belief, Defendants have begun or will imminently begin marketing the Accused Products.

50. On information and belief, Defendants' efforts to commercialize the Accused Product are constant and all-encompassing.

51. On information and belief, Defendants are unwavering in their commitment to commercialize the Accused Product.

52. On information and belief, Defendants have commercial plans for an upcoming launch of the Accused Product.

53. On information and belief, Defendants are currently manufacturing, or directing and controlling the manufacture of, and/or are actively preparing to manufacture or direct and

control the manufacture of, and/or will imminently manufacture or direct and control the manufacture of, the Accused Product, so that the product can be offered for sale and sold in the United States and in this District.

54. On information and belief, Defendants intend that, following manufacture of the Accused Product, one or more of the Defendants will sell, distribute, and/or direct the sale and distribution of, the Accused Product under NDA No. 215700 that is, or will be, manufactured by or at the direction of Defendants.

55. On information and belief, Defendants have begun a concerted effort to offer for sale and sell the Accused Product before the expiration of the patents-in-suit asserted in this action.

56. As set forth in Counts I-VI below, the actual and/or imminent manufacture of the Accused Product infringes one or more claims of the patents-in-suit, *e.g.*, for treating acute hypotension.

57. On information and belief, Defendants were aware of and tracked the patents-in-suit through prosecution thereof at the United States Patent and Trademark Office.

58. On information and belief, Defendants were aware of and had knowledge of the allowed claims that have now issued as part of the patents-in-suit, and Defendants have been aware of Nevakar Injectables' issued '436 Patent since March 12, 2019, '735 Patent since September 24, 2019, and '850 Patent since February 25, 2020. Despite that knowledge of the patents-in-suit, Defendants have indicated no intent to stop their actually occurring or imminent infringing activity described above.

COUNT I
INFRINGEMENT OF THE '436 PATENT

59. Nevakar Injectables incorporates and realleges Paragraphs 1-58 above.

60. On information and belief, Defendants manufacture, use, sell, offer for sale, or import the Accused Product for sale in the United States, and these acts directly and/or indirectly infringe one or more claims of the ’436 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

61. On information and belief, the Accused Product and the use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, infringes directly and/or indirectly infringes one or more claims of the ’436 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

62. Individually and collectively, Defendants’ manufacture, use, sale, offer for sale, or importation, of the Accused Product in the United States constitutes infringement of one or more claims of the ’436 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

63. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions constitutes direct infringement of the ’436 Patent.

64. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions are inducing infringement of the ’436 Patent.

65. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions are contributing to the infringement of the ’436 Patent.

66. The ’436 Patent has 19 claims directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

67. As one example, independent claim 1 of the ’436 Patent is directed to:

A ready-to-administer norepinephrine composition, comprising:

> an aqueous acidic solution having a pH range of between 3.7 and 4.3, wherein the aqueous acidic solution further comprises a chelating agent and a pharmaceutically acceptable salt;
>
> wherein the chelating agent is present in an amount of between 1 µg/ml and 100 µg/ml, and wherein the pharmaceutically acceptable salt is present in an amount of between 0.6 wt % and 1.2 wt %;
>
> norepinephrine dissolved at a concentration suitable for administration to a patient in need thereof, wherein the norepinephrine is an R-isomer;
>
> wherein the ready-to-administer norepinephrine composition is substantially free of antioxidants; and
>
> wherein the ready-to-administer norepinephrine composition is formulated such that after storage over at least three months equal or less than 10% of the R-isomer form will isomerize to the S-isomer and such that equal or less than 5% of the total norepinephrine will degrade to degradation products.

68. Consistent with this claim, and based on publicly available information including the FDA-approved product label (**Exhibit B**), and on information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product meets each and every limitation of claim 1 of the ’436 Patent literally or equivalently, and Defendants directly and/or indirectly infringe that claim under 35 U.S.C. § 271(a), (b), (c), and/or (g). Upon information and belief, Defendants directly infringe the claims of the ’436 Patent because each element of the claims thereof is found in the Accused Product. Upon information and belief, Defendants indirectly infringe the ’436 Patent by actively, knowingly and intentionally aiding, abetting, directing, encouraging, or otherwise instructing third parties and knowingly inducing third parties, including contract manufacturers, to commit acts that constitute infringement of the ’436 Patent.

69. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the '436 Patent and no reasonable basis for believing that the infringed claims are invalid.

70. Defendants' manufacture, use, sale, offer for sale, or importation of the Accused Product constitutes willful infringement.

71. This case is "exceptional," and Nevakar Injectables is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

72. The acts of infringement by Defendants set forth above will cause Nevakar Injectables irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

73. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the '436 Patent.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '436 PATENT

74. Nevakar Injectables incorporates and realleges Paragraphs 1-73 above.

75. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271(a), (b), (c), and/or (g), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. To the extent that Defendants contend that there has been no manufacture, use, sale, offer for sale, or importation of the Accused Product at this time, there is still an actual case or controversy such that the Court may entertain Nevakar Injectables' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

77. Upon information and belief, the FDA's approval of the Accused Product, coupled with Defendants' commercial activities in support of the imminent manufacture, importation and/or launch of the Accused Product, including at least: (i) Defendants' application to, and approval from, the FDA for permission to market their Product; (ii) Defendants indications that they have commenced or will imminently commence marketing the Accused Product ; (iii) and Defendants' commitment to commercializing the Accused Product, create an actual, immediate, and real controversy under the Declaratory Judgment Act that Defendants will directly infringe, actively induce, and/or contribute to the infringement of valid and enforceable claims of the '436 Patent before the patent's expiration in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g).

78. On information and belief, Defendants have engaged in and will continue to engage in substantial activities in preparation to manufacture and market the Accused Product in the United States.

79. On information and belief, Defendants will imminently manufacture, use, sell, offer for sale, or import the Accused Product, and these acts directly and/or indirectly will infringe one or more claims of the '436 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

80. On information and belief, the Accused Product and the imminent use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, will infringe directly and/or indirectly infringe one or more claims of the '436 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

81. Individually and collectively, Defendants' imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute infringement of one or more claims of the '436 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

82. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions will constitute direct infringement of the ’436 Patent.

83. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions will constitute induced infringement of the ’436 Patent.

84. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’436 Patent, and one or more of Defendants’ actions will constitute contributory infringement of the ’436 Patent.

85. The imminent acts of infringement by Defendants set forth above will cause Nevakar Injectables substantial and irreparable harm for which it has no adequate remedy at law.

86. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the ’436 Patent and no reasonable basis for believing that those claims are invalid.

87. Defendants’ imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute willful infringement.

88. This case is exceptional, and Nevakar Injectables is entitled to an award of attorney fees under 35 U.S.C. § 285.

89. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

90. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the ’436 Patent.

COUNT III
INFRINGEMENT OF THE '735 PATENT

91. Nevakar Injectables incorporates and realleges Paragraphs 1-90 above.

92. On information and belief, Defendants manufacture, use, sell, offer for sale, or import the Accused Product for sale in the United States, and these acts directly and/or indirectly infringe one or more claims of the '735 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

93. On information and belief, the Accused Product and the use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, infringes directly and/or indirectly infringes one or more claims of the '735 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

94. Individually and collectively, Defendants' manufacture, use, sale, offer for sale, or importation, of the Accused Product in the United States constitutes infringement of one or more claims of the '735 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

95. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions constitutes direct infringement of the '735 Patent.

96. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions are inducing infringement of the '735 Patent.

97. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions are contributing to the infringement of the '735 Patent.

98. The ’735 Patent has 22 claims directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

99. As one example, independent claim 1 of the ’735 Patent is directed to:

A method of treating hypotension, comprising:

> administering a ready-to-administer norepinephrine composition at an initial dose per minute;
>
> administering the norepinephrine composition at a maintenance dose per minute, wherein the initial dose per minute is greater than the maintenance dose per minute;
>
> wherein the initial dose per minute is a dose of between 8 and 12 µg/min, and wherein the maintenance dose per minute is a dose of between 2 and 4 µg/min;
>
> wherein the norepinephrine composition comprises norepinephrine or a salt thereof at a concentration of between 10 µg/ml and 100 µg/ml in an aqueous acidic solution having a pH range of between 3.7 and 4.3, wherein the aqueous acidic solution further comprises a chelating agent at a concentration of between 1 µg/ml and 100 µg/ml and a tonicity agent;
>
> wherein the norepinephrine composition is substantially free of antioxidants; and
>
> wherein the norepinephrine or a salt thereof in the norepinephrine composition comprises at least about 90% R-isomer of norepinephrine after storage at 25±2° C. and 60±5% relative humidity, over at least three months as determined by HPLC.

100. Consistent with this claim, and based on publicly available information including the FDA-approved product label (**Exhibit B**), and on information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product meets each and every limitation of claim 1 of the ’735 Patent literally or equivalently, and Defendants directly and/or indirectly infringe that claim under 35 U.S.C. § 271(a), (b), (c), and/or (g). Upon information and belief, Defendants directly infringe the claims of the ’735 Patent because each element of the claims thereof is found in the Accused Product. Upon information and belief, Defendants indirectly

infringe the '735 Patent by actively, knowingly and intentionally aiding, abetting, directing, encouraging, or otherwise instructing third parties and knowingly inducing third parties, including contract manufacturers, to commit acts that constitute infringement of the '735 Patent.

101. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the '735 Patent and no reasonable basis for believing that the infringed claims are invalid.

102. Defendants' manufacture, use, sale, offer for sale, or importation of the Accused Product constitutes willful infringement.

103. This case is "exceptional," and Nevakar Injectables is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

104. The acts of infringement by Defendants set forth above will cause Nevakar Injectables irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

105. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the '735 Patent.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '735 PATENT

106. Nevakar Injectables incorporates and realleges Paragraphs 1-105 above.

107. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271(a), (b), (c), and/or (g), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

108. To the extent that Defendants contend that there has been no manufacture, use, sale, offer for sale, or importation of the Accused Product at this time, there is still an actual case

or controversy such that the Court may entertain Nevakar Injectables' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

109. Upon information and belief, the FDA's approval of the Accused Product, coupled with Defendants' commercial activities in support of the imminent manufacture, importation and/or launch of the Accused Product, including at least: (i) Defendants' application to, and approval from, the FDA for permission to market their Product; (ii) Defendants indications that they have commenced or will imminently commence marketing the Accused Product; (iii) and Defendants' commitment to commercializing the Accused Product, create an actual, immediate, and real controversy under the Declaratory Judgment Act that Defendants will directly infringe, actively induce, and/or contribute to the infringement of valid and enforceable claims of the '735 Patent before the patent's expiration in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g).

110. On information and belief, Defendants have engaged in and will continue to engage in substantial activities in preparation to manufacture and market the Accused Product in the United States.

111. On information and belief, Defendants will imminently manufacture, use, sell, offer for sale, or import the Accused Product, and these acts directly and/or indirectly will infringe one or more claims of the '735 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

112. On information and belief, the Accused Product and the imminent use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, will infringe directly and/or indirectly infringe one or more claims of the '735 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

113. Individually and collectively, Defendants' imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute infringement of one or more claims of the '735 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

114. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions will constitute direct infringement of the '735 Patent.

115. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions will constitute induced infringement of the '735 Patent.

116. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '735 Patent, and one or more of Defendants' actions will constitute contributory infringement of the '735 Patent.

117. The imminent acts of infringement by Defendants set forth above will cause Nevakar Injectables substantial and irreparable harm for which it has no adequate remedy at law.

118. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the '735 Patent and no reasonable basis for believing that those claims are invalid.

119. Defendants' imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute willful infringement.

120. This case is exceptional, and Nevakar Injectables is entitled to an award of attorney fees under 35 U.S.C. § 285.

121. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

122. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the ’735 Patent.

COUNT V
INFRINGEMENT OF THE ’850 PATENT

123. Nevakar Injectables incorporates and realleges Paragraphs 1-122 above.

124. On information and belief, Defendants manufacture, use, sell, offer for sale, or import the Accused Product for sale in the United States, and these acts directly and/or indirectly infringe one or more claims of the ’850 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

125. On information and belief, the Accused Product and the use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, infringes directly and/or indirectly infringes one or more claims of the ’850 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

126. Individually and collectively, Defendants’ manufacture, use, sale, offer for sale, or importation, of the Accused Product in the United States constitutes infringement of one or more claims of the ’850 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

127. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’850 Patent, and one or more of Defendants’ actions constitutes direct infringement of the ’850 Patent.

128. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’850 Patent, and one or more of Defendants’ actions are inducing infringement of the ’850 Patent.

129. On information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the '850 Patent, and one or more of Defendants' actions are contributing to the infringement of the '850 Patent.

130. The '850 Patent has 19 claims directed to compositions and methods for ready-to-inject norepinephrine compositions with improved stability.

131. As one example, independent claim 1 of the '850 Patent is directed to:

> A sterile, ready-to-administer, packaged norepinephrine composition, comprising:
>
> > a container filled with a sterile, ready-to-administer norepinephrine composition and packaged in a secondary container;
> >
> > wherein the sterile, ready-to-administer norepinephrine composition comprises norepinephrine or a salt thereof in an amount of between 10 μg/ml and 100 μg/ml, a chelating agent in an amount of between 1 μg/ml and 100 μg/ml, a tonicity adjusting agent in an amount of between 0.6 wt % and 1.2 wt %, and an aqueous acidic solution, wherein the norepinephrine comprises at least 95% of R-isomer of norepinephrine;
> >
> > wherein the sterile, ready-to-administer norepinephrine composition is substantially free of antioxidants;
> >
> > wherein the sterile, ready-to-administer norepinephrine composition has a pH of between 3.7 and 4.3; and
> >
> > wherein the sterile, ready-to-administer, packaged norepinephrine composition comprises at least about 90% R-isomer of norepinephrine after storage at 25±2° C. and 60±5% relative humidity, over at least three months as determined by HPLC.

132. Consistent with this claim, and based on publicly available information including the FDA-approved product label (**Exhibit B**), and on information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Product meets each and every limitation of claim 1 of the '850 Patent literally or equivalently, and Defendants directly and/or indirectly infringe that claim under 35 U.S.C. § 271(a), (b), (c), and/or (g). Upon information and belief,

Defendants directly infringe the claims of the ’850 Patent because each element of the claims thereof is found in the Accused Product. Upon information and belief, Defendants indirectly infringe the ’850 Patent by actively, knowingly and intentionally aiding, abetting, directing, encouraging, or otherwise instructing third parties and knowingly inducing third parties, including contract manufacturers, to commit acts that constitute infringement of the ’850 Patent.

133. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the ’850 Patent and no reasonable basis for believing that the infringed claims are invalid.

134. Defendants’ manufacture, use, sale, offer for sale, or importation of the Accused Product constitutes willful infringement.

135. This case is “exceptional,” and Nevakar Injectables is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

136. The acts of infringement by Defendants set forth above will cause Nevakar Injectables irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

137. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the ’850 Patent.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’850 PATENT

138. Nevakar Injectables incorporates and realleges Paragraphs 1-137 above.

139. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271(a), (b), (c), and/or (g), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

140. To the extent that Defendants contend that there has been no manufacture, use, sale, offer for sale, or importation of the Accused Product at this time, there is still an actual case or controversy such that the Court may entertain Nevakar Injectables' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

141. Upon information and belief, the FDA's approval of the Accused Product, coupled with Defendants' commercial activities in support of the imminent manufacture, importation and/or launch of the Accused Product, including at least: (i) Defendants' application to, and approval from, the FDA for permission to market their Product; (ii) Defendants' indications that they have commenced or will imminently commence marketing the Accused Product; (iii) and Defendants' commitment to commercializing the Accused Product, create an actual, immediate, and real controversy under the Declaratory Judgment Act that Defendants will directly infringe, actively induce, and/or contribute to the infringement of valid and enforceable claims of the '850 Patent before the patent's expiration in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g).

142. On information and belief, Defendants have engaged in and will continue to engage in substantial activities in preparation to manufacture and market the Accused Product in the United States.

143. On information and belief, Defendants will imminently manufacture, use, sell, offer for sale, or import the Accused Product, and these acts directly and/or indirectly will infringe one or more claims of the '850 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

144. On information and belief, the Accused Product and the imminent use of the Accused Product in accordance with, and as directed by, its FDA-approved product label, will

infringe directly and/or indirectly infringe one or more claims of the ’850 Patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

145. Individually and collectively, Defendants’ imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute infringement of one or more claims of the ’850 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

146. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’850 Patent, and one or more of Defendants’ actions will constitute direct infringement of the ’850 Patent.

147. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’850 Patent, and one or more of Defendants’ actions will constitute induced infringement of the ’850 Patent.

148. On information and belief, the imminent manufacture, use, sale, offer for sale, or importation of the Accused Product is covered by the claims of the ’850 Patent, and one or more of Defendants’ actions will constitute contributory infringement of the ’850 Patent.

149. The imminent acts of infringement by Defendants set forth above will cause Nevakar Injectables substantial and irreparable harm for which it has no adequate remedy at law.

150. On information and belief, Defendants have no reasonable basis for believing that the Accused Product will not infringe one or more valid claims of the ’850 Patent and no reasonable basis for believing that those claims are invalid.

151. Defendants’ imminent manufacture, use, sale, offer for sale, or importation of the Accused Product will constitute willful infringement.

152. This case is exceptional, and Nevakar Injectables is entitled to an award of attorney fees under 35 U.S.C. § 285.

153. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

154. Nevakar Injectables is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, selling, or importing the Accused Product in the United States before expiration of the ’850 Patent.

PRAYER FOR RELIEF

WHEREFORE, Nevakar Injectables respectfully requests the following relief:

A. A judgment, pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g), that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of the Accused Product before the expiration of the ’436 Patent (including any regulatory extension), has infringed the ’436 Patent;

B. A declaration, pursuant to 28 U.S.C. §§ 2201 and 2202, that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of the Accused Product will infringe the ’436 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g);

C. A judgment that the ’436 Patent is valid and enforceable;

D. A judgment, pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g), that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of the Accused Product before the expiration of the ’735 Patent (including any regulatory extension), has infringed the ’735 Patent;

E. A declaration, pursuant to 28 U.S.C. §§ 2201 and 2202, that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the

United States, of the Accused Product will infringe the ’735 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g);

F. A judgment that the ’735 Patent is valid and enforceable;

G. A judgment, pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g), that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of the Accused Product before the expiration of the ’850 Patent (including any regulatory extension), has infringed the ’850 Patent;

H. A declaration, pursuant to 28 U.S.C. §§ 2201 and 2202, that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States, of the Accused Product will infringe the ’850 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g);

I. A judgment that the ’850 Patent is valid and enforceable;

J. An order for preliminary and permanent injunction for Defendants’ unlawful conduct;

K. An award, pursuant to 35 U.S.C. § 284, of damages or other monetary relief to compensate Nevakar Injectables for Defendants’ engagement in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accused Product, or any product the making, using, offering for sale, sale, marketing, distribution, and/or importation of which infringes the ’436 Patent, the ’735 Patent, and the ’850 Patent;

L. Awarding Nevakar Injectables enhanced damages;

M. A judgment pursuant to 35 U.S.C. § 285 that this case against Defendants is an exceptional case and an award of attorneys’ fees and costs; and

N. Such other and further relief to Nevakar Injectables as this Court may deem just and proper.

Respectfully submitted,

LOMBARD & GELIEBTER LLP

Dated: November 29, 2022
New York, New York

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