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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NEVAKAR INJECTABLES, INC. and LONG GROVE PHARMACEUTICALS, LLC, *Plaintiffs,* v. INFORLIFE SA and WG CRITICAL CARE, LLC. *Defendants.*	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Nevakar Injectables, Inc. ("Nevakar") and Long Grove Pharmaceuticals, LLC ("Long Grove") (collectively, "Plaintiffs"), by and through their undersigned attorneys, hereby bring this action against Defendants InfoRLife SA ("InfoRLife") and WG Critical Care, LLC ("WG Critical Care") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 12,245,996 ("the '996 Patent" or "Patent-in-Suit") arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

THE PARTIES

2. Plaintiff Nevakar is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1019 US Highway 202 #206, Bridgewater, NJ 08807.

3. Plaintiff Long Grove is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 9450 W Bryn Mawr Ave, Rosemont, Illinois 60018.

4. Long Grove is the exclusive licensee of the Patent-in-Suit pursuant to an *Exclusive License and Marketing Agreement By and Between Long Grove Pharmaceuticals, LLC and Nevakar Injectables, Inc*., dated May 4, 2023 ("Exclusive License Agreement").

5. Upon information and belief, Defendant 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.

6. Upon 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.

7. Upon 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. Upon 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

8. This Court has subject-matter jurisdiction over this action 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.)*.

9. This Court has personal jurisdiction over Defendant 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.

10. This Court has personal jurisdiction over Defendant 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.

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

12. 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.

13. 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.

14. 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.). Defendants also did not contest personal jurisdiction in the matter of *Nevakar Injectables, Inc. v. InfoRLife SA*, No. 2:22-cv-06886-JXN-SDA (D.N.J).

15. This Court 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. 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 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.

16. Venue is proper in this judicial district as to WG Critical Care under 28 U.S.C. §§ 1391 and/or 1400(b) at least because, WG Critical Care is a corporation organized and existing under the laws of the state of New Jersey and is subject to personal jurisdiction in this Judicial District.

17. Venue is proper in this judicial 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.

LONG GROVE'S NOREPINEPHRINE PRODUCT AND THE PATENT-IN-SUIT

18. Nevakar is the owner and assignee of the '996 Patent, subject to the Exclusive License Agreement.

19. On or around May 4, 2023, Long Grove executed the Exclusive License Agreement, granting Long Grove an exclusive license to certain Nevakar patents and any patents claiming priority to those patents, which includes the '996 Patent, for the commercialization of norepinephrine bitartrate products. The Exclusive License Agreement provides Long Grove the right to sue for infringement of the licensed patents, including the '996 Patent.

20. Long Grove is the holder of New Drug Application ("NDA") No. 214628 for FDA-approved norepinephrine in sodium chloride injection. Long Grove manufactures, markets, and sells three strengths of products: 4 mg (16 µg/ml), 8 mg (32 µg/ml), and 16 mg (64 µg/ml) norepinephrine bitartrate (the "Long Grove Products"), each of which is stored in 250 mL infusion bags.

21. On March 11, 2025, the '996 patent, titled "Norepinephrine Compositions and Methods Therefor," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). A true copy of the '996 Patent is attached as Exhibit A.

22. The '996 Patent issued from U.S. Application No. 17/861,752 ("the '752 Application"), filed on July 11, 2022, which is a divisional of U.S. Patent Application Nos. 16/839,450, 16/239,465, and 15/883,798 and claims priority from provisional application No. 62/452,220.

DEFENDANTS' NOREPINEPHRINE BITARTRATE PRODUCTS

23. On November 19, 2021, InfoRLife filed NDA No. 215700 under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FDCA") for three strengths of ready-to-administer formulations of norepinephrine bitartrate in 0.9% sodium chloride: 4 mg (16 µg/ml), 8 mg (32 µg/ml), and 16 mg (64 µg/ml) norepinephrine bitartrate, each of which is stored in a 250 mL infusion bag. The three strengths (4 mg (16 µg/ml), 8 mg (32 µg/ml), and 16 mg (64

µg/ml)) are collectively referred to as the "Accused Products". FDA approved that NDA on September 15, 2022 for restoration of blood pressure in adult patients with acute hypotensive states.

24. The label for the Accused Products states that the Accused Products contain "9 mg of Sodium Chloride USP as tonicity agent, and may contain Hydrochloric Acid NF and Sodium Hydroxide NF as pH adjusters, for the pH range of 3.4 to 4.0, in Water for Injection." Further, the norepinephrine bitartrate used in the Accused Products is a chiral compound in the R-configuration. The Accused Products are substantially free of an antioxidant.

25. Defendants have offered to sell, entered into contracts to sell, and sold the Accused Products beginning on or around October 31, 2022.

COUNT ONE
Defendants' Infringement of the '996 Patent

26. Plaintiffs re-allege and incorporate each of the preceding paragraphs as if fully set forth herein.

27. Defendants' commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of the Accused Products constitutes infringement of one or more claims of the '996 Patent, literally and/or under the doctrine of the equivalents, under 35 U.S.C. § 271, *et. seq*.

28. The claims of the '996 Patent are directed to storage stable ready-to-inject norepinephrine compositions and methods of preparing storage stable ready-to-inject norepinephrine compositions.

29. As one example, claim 1 of the '996 Patent recites:

A sterile storage stable ready-to-inject norepinephrine composition, comprising:

an aqueous pharmaceutically acceptable solution containing norepinephrine, a tonicity agent, and a metal ion chelator;

wherein the composition contains the norepinephrine in an amount of equal or less than 100 µg/ml;

wherein the norepinephrine is present as an R-isomer in an amount of at least at least 90% of total norepinephrine;

wherein the aqueous solution comprises the metal ion chelator in an amount of between 1 µg/ml and 100 µg/ml, and wherein the metal ion chelator is a bicarboxylic acid;

wherein the tonicity agent is selected from the group consisting of a pharmaceutically acceptable salt, glycerol, a sugar alcohol, and a sugar; and

wherein the pH of the aqueous solution is in a range of between 3.7-5.0, and wherein the composition is substantially antioxidant-free.

30. Consistent with this claim, and based on publicly available information, including the FDA-approved label, and on information and belief, the manufacture, use, sale, offer for sale, or importation of the Accused Products meets each and every limitation of claim 1 of the'996 Patent literally or equivalently, and therefore Defendants directly and/or indirectly infringe under 35 U.S.C. §271 (a), (b), and/or (c).

31. Upon information and belief, Defendants directly infringe one or more claims of the '996 Patent because each element of one or more claims thereof is found in the Accused Products.

32. Upon information and belief, Defendants indirectly infringe one or more claims of the '996 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 '996 Patent.

33. Each of the Accused Products are sterile storage stable ready-to-inject norepinephrine composition.

34. Each of the Accused Products are aqueous pharmaceutically acceptable solutions that contain norepinephrine, a tonicity agent and a metal ion chelator.

35. The Accused Products' Labels state that each mL contains the equivalent of 16, 32, or 64 micrograms of norepinephrine base. Therefore, The Accused Products each contain norepinephrine in an amount of equal or less than 100 µg/ml. Upon information and belief, the norepinephrine in the Accused Products is present as an *R*-isomer in an amount of at least at least 90% of total norepinephrine.

36. The Accused Products contain sodium chloride, which is a salt and a tonicity agent.

37. The Accused Products contain dissociated bitartrate anions that originated from the norepinephrine bitartrate. As recognized by the Patent Examiner during the prosecution of the '996 Patent, bitartrate that originates from the norepinephrine bitartrate functions as a metal ion chelator and is a bicarboxylic acid within the meaning of the claims of the '996 Patent. Exhibit B at Nev-Norepi_0775780.

38. The Accused Products have a pH in a range of between 3.7-5.0.

39. The Accused Products are substantially antioxidant-free.

40. Plaintiffs are entitled to a judgment that the commercial manufacture, use, offer to sell, or sale withing the United States, and/or importation into the United States, of the Accused Products, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Accused Products before expiration of the '996 Patent by Defendants or their agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '996 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, inducing, or contributing to infringement of the ’996 Patent. Plaintiffs do not have an adequate remedy at law to fully compensate Plaintiffs for their damages.

42. Defendants’ infringement of the ’996 Patent is willful, entitling Plaintiffs to enhanced damages.

43. This case is an exceptional and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter:

A. A judgment that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the Accused Products infringes the ’996 Patent under 35 U.S.C. § 271 (a), (b), and/or (c);

B. A judgment that the ’996 Patent is valid and enforceable;

C. An order permanently enjoining Defendants, their officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing any of the ’996 Patent claims, either directly, by inducement, or by contribution;

D. An award pursuant to 35 U.S.C. §284, of damages and other monetary relief to compensate Plaintiffs for Defendants’ engagement in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accused Products, or any product the making, using, offering for sale, sale, marketing, distribution, and/or importation of which infringes the ’996 Patent;

E. An award for enhanced damages;

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

G. Such other and further relief to Plaintiffs as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs Nevakar Injectables, Inc. and Long Grove Pharmaceuticals, LLC demand a trial by jury with respect to all issues that are triable to a jury as a matter of right.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Plaintiffs hereby certifies that the matter in controversy is the subject of another pending action for patent infringement of U.S. Patent Nos. 10,226,436, 10,420,735, 10,471,026, 10,568,850, 10,646,458, 11,413,259 and 11,602,508:

● *Nevakar Injectables, Inc. and Long Grove Pharmaceuticals, LLC v.InfoRLife SA and WG Critical Care, LLC,* Civil Action No. 2:22-cv-6886 (D.N.J.).

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Respectfully submitted,

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