IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVAKAR INJECTABLES, INC. and LONG GROVE PHARMACEUTICALS, LLC, *Plaintiffs*, v. BAXTER HEALTHCARE CORP. *Defendant.*	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 Defendant Baxter Healthcare Corp. ("Baxter"), 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 Baxter is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

JURISDICTION AND VENUE

6. 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.)*.

7. This Court has personal jurisdiction over Baxter because it is incorporated in the state of Delaware and has designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

8. This Court has personal jurisdiction over Baxter because this suit arises out of and relates to its activities that are, and will be, directed to the State of Delaware.

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

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

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

11. 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.

12. 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.

13. 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.

14. 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.

BAXTER'S NOREPINEPHRINE BITARTRATE PRODUCTS

15. On March 16, 2020, Baxter filed NDA No. 214313 under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FDCA") for two strengths of ready-to-administer formulations of norepinephrine bitartrate in 5% dextrose: 4 mg (16 µg/ml) and 8 mg (32 µg/ml) norepinephrine bitartrate, each of which is stored in a 250 mL infusion bag. FDA approved that NDA on January 15, 2021 for restoration of blood pressure in adult patients with acute hypotensive states.

16. Baxter filed supplemental NDA No. 214313/S-003 under section 505(b)(2) of the FDCA on May 26, 2023 (Baxter Supplement Approval), seeking the addition of a 16 mg/250 mL (64 µg/ml) strength for the same indication, route of administration, dosage form and dosing regimen as the currently approved presentations. 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 "Baxter Products".

17. The label for Baxter's Products states that the Baxter Products contains "dextrose monohydrate (50 mg/mL) and may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. It has a target pH of 3.7." Further, the norepinephrine bitartrate used in the Baxter Products is a chiral compound in the R-configuration. The Baxter Products are substantially free of an antioxidant.

18. Baxter has offered to sell, entered into contracts to sell, and sold the Baxter Products beginning on or around September 23, 2021.

COUNT ONE
Baxter's Infringement of the '996 Patent

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

20. Baxter's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of the Baxter 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*.

21. 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.

22. 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.

23. 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 Baxter Products meets each and every limitation of claim 1 of the'996 Patent literally or equivalently, and therefore Baxter directly and/or indirectly infringes under 35 U.S.C. §271 (a), (b), (c), and/or (g).

24. Upon information and belief, Baxter directly infringes one or more claims of the '996 Patent because each element of one or more claims thereof is found in the Baxter Products.

25. Upon information and belief, Baxter indirectly infringes 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.

26. Each of the Baxter Products are sterile storage stable ready-to-inject norepinephrine compositions.

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

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

29. Baxter's Products contain dextrose, which is a sugar and a tonicity agent.

30. Baxter's 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 p.4.

31. The Baxter Products have a pH in a range of between 3.7-5.0.

32. The Baxter Products are substantially antioxidant-free.

33. 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 Baxter 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 Baxter Products before expiration of the '996 Patent by Baxter or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '996 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

34. Plaintiffs will be irreparably harmed if Baxter is 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.

35. Baxter's infringement of the '996 Patent is willful, entitling Plaintiffs to enhanced damages.

36. 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 Baxter Products infringes the '996 Patent under 35 U.S.C. § 271 (a), (b), (c), and/or (g);

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

C. An order permanently enjoining Baxter, its 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 Baxter's engagement in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Baxter 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.

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