IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

ENDO VENTURES LIMITED and PAR STERILE PRODUCTS, LLC, *Plaintiffs*, v. NEXUS PHARMACEUTICALS, INC., *Defendant*.	Case No. 2:23-cv-299

COMPLAINT

Plaintiffs Endo Ventures Limited ("Endo") and Par Sterile Products, LLC ("Par Sterile") (collectively, "Plaintiffs"), for their complaint against Defendant Nexus Pharmaceuticals, Inc. ("Nexus"), allege as follows:

NATURE AND SUMMARY OF THIS ACTION

1. This is an action for patent infringement arising under 35 U.S.C. § 271 regarding Defendant Nexus's infringement of Plaintiffs' U.S. Patent Nos. 10,869,845 ("the '845 patent") and 11,491,121 ("the '121 patent") by manufacturing, using, offering for sale, or selling within the United States, and/or importing into the United States Nexus's ready-to-use ephedrine syringe products.

THE PARTIES

2. Endo is an Irish company with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

3. Par Sterile is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, New Jersey 07677.

4. Upon information and belief, Nexus is a corporation organized and existing under the laws of the state of Illinois, having a principal place of business at 400 Knightsbridge Parkway, Lincolnshire, IL 60069.

5. Upon information and belief, Nexus is a healthcare company and pharmaceutical manufacturer that develops, manufactures, markets and/or distributes pharmaceutical products around the United States, including in this judicial district.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Nexus at least because Nexus has a place of business at 10300 128th Avenue, Pleasant Prairie, Wisconsin 53158.

8. This Court has personal jurisdiction over Nexus at least because Nexus has continuous and systematic contacts within this judicial district. On information and belief, Nexus develops, manufactures, seeks approval for, and sells certain FDA-approved pharmaceutical products that are regularly marketed and sold in Wisconsin. On further information and belief, Nexus has a manufacturing facility in Pleasant Prairie, Wisconsin, which is within this judicial district.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b). On information and belief, Nexus has a regular and established place of business in this judicial district. On further information and belief, Nexus has committed acts of infringement in this judicial district, including but not limited to selling and/or offering for sale products that infringe, or were made by a process that infringes, one or more claims of the ’845 and ’121 patents.

THE PATENTS-IN-SUIT

10. The ’845 patent, titled “Ephedrine Compositions and Methods,” was duly and legally issued by the United States Patent and Trademark Office on December 22, 2020. A true and correct copy of the ’845 patent is attached as Exhibit A.

11. Endo is an exclusive licensee of the ’845 patent and has sublicensed certain of its rights to its affiliate, Par Sterile. As an exclusive licensee having all substantial rights to the ’845 patent, Endo has the ability and proper standing to enforce the ’845 patent.

12. The ’121 patent, titled “Ephedrine Compositions and Methods,” was duly and legally issued by the United States Patent and Trademark Office on November 8, 2022. A true and correct copy of the ’121 patent is attached as Exhibit B.

13. Endo is an exclusive licensee of the ’121 patent and has sublicensed certain of its rights to its affiliate, Par Sterile. As an exclusive licensee having all substantial rights to the ’121 patent, Endo has the ability and proper standing to enforce the ’121 patent.

ENDO’S READY-TO-USE EPHEDRINE SULFATE PRODUCTS

14. Endo is the holder of New Drug Application (“NDA”) No. 213994 for ephedrine sulfate injection, 5 mg/mL, in glass vials (“Endo’s Ephedrine RTU Vials”), which the U.S. Food and Drug Administration (“FDA”) approved on October 16, 2020. Par Sterile began commercial marketing of Endo’s Ephedrine RTU Vials in March 2022.

15. Endo is also the holder of a supplement to NDA No. 213994 for ephedrine sulfate injection, 5 mg/mL, in prefilled syringes (“Endo’s Ephedrine RTU Syringes,” and, together with Endo’s Ephedrine RTU Vials, “Endo’s Ephedrine Products”), which FDA approved on April 22, 2022.

16. Endo’s Ephedrine Products are ready-to-use (“RTU”) formulations, stored in either glass vials or prefilled syringes, that require no further dilution prior to administration to a

patient. Endo's Ephedrine Products are indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

17. FDA-approved, ready-to-use formulations of ephedrine were not commercially available prior to the effective filing date of the '845 and '121 patents. Then-available FDA-approved ephedrine products were concentrated formulations that had to be diluted prior to administration to a patient. The diluted solutions of ephedrine were not pH stable and, therefore, were not recommended to be stored for any period of time.

18. The '845 and '121 patents describe stable, ready-to-administer ephedrine products that avoid the need for dilution prior to use and can be stored for up to 24 months. Avoiding the dilution step provides many benefits for hospitals, including avoiding the potential for dilution errors, avoiding the risk of contamination, and saving time and resources.

NEXUS'S READY-TO-USE EPHEDRINE SULFATE PRODUCTS

19. Nexus is the holder of NDA No. 213407 for ephedrine sulfate injection, 5 mg/mL, in glass vials ("Nexus's Emerphed RTU Vials"), which the FDA approved on April 17, 2020.

20. Nexus filed a complaint in the District of New Jersey on August 17, 2021 seeking declaratory judgment that Nexus's Emerphed RTU Vials do not infringe the '845 patent. *See Nexus Pharm., Inc. v. Nevakar, Inc. et al.*, No. 21-cv-15524 (D.N.J. filed Aug. 17, 2021). That action ultimately settled.

21. On information and belief, Nexus then filed a supplement to its NDA No. 213407 for ephedrine sulfate injection, 5 mg/mL, in 5 mL and 10 mL prefilled syringes ("Nexus's Emerphed RTU Syringes"), which FDA approved on March 1, 2023. (*See* Nexus Press Release (Mar. 1, 2023) (attached as Exhibit C).)

22. On October 17, 2022, counsel for Endo and Par Sterile contacted counsel for Nexus and requested confidential access to regulatory filings related to Nexus's Emerphed RTU

Syringes. On October 26, 2022, counsel for Nexus declined that request and asserted that Nexus has no obligation to disclose to Endo any information regarding any of its products or potential products. On March 1, 2023, after Nexus announced that it had received FDA approval for Nexus's Emerphed RTU Syringes, counsel for Endo and Par Sterile renewed their request for confidential access to regulatory filings related to Nexus's Emerphed RTU Syringes. On March 3, 2023, counsel for Nexus declined that renewed request.

23. A true and correct copy of the labeling for Nexus's Emerphed RTU Syringes is attached as Exhibit E and available at https://21078818.fs1.hubspotusercontent-na1.net/hubfs/21078818/EMERPHEDPFSPI.pdf (last accessed March 3, 2023).

24. A true and correct copy of the FDA-approved labeling for Nexus' Emerphed RTU Vials as of April 2020 is attached as Exhibit D and available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213407s000lbl.pdf (last accessed March 3, 2023).

25. On information and belief, Nexus has offered for sale and/or sold, presently offers for sale and/or has sold, and/or imminently intends to offer for sale and/or sell Nexus's Emerphed RTU Syringes to one or more customers throughout the United States, including in this judicial district. (*See* Ex. C ("'In 2020, we were the first manufacturer to launch an FDA-approved ephedrine sulfate injection in a ready-to-use vial. Since that time, the market has changed and refined itself, so we are incredibly excited to introduce the next generation of ready-to-administer ephedrine sulfate products once again,' said Omair Ahmed, Chief Operating Officer.").) On further information and belief, Nexus's Emerphed RTU Syringes are "available immediately in cartons of ten single-dose syringes." (*See id.*)

26. On information and belief, Nexus listed pricing information for Nexus's Emerphed RTU Syringes in the industry source, Medi-Span® Price Rx® Pro Plus, with an effective date of March 5, 2023.

27. On information and belief, Nexus's Emerphed RTU Syringes are manufactured in Italy for Nexus and subsequently imported into the United States by or for Nexus. (*See* Ex. E at § 16.)

COUNT I
INFRINGEMENT OF THE '845 PATENT

28. Plaintiffs re-allege and incorporate Paragraphs 1-27 as if fully set forth herein.

29. Nexus's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Nexus's Emerphed RTU Syringes constitutes infringement of at least claim 1 of the '845 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

30. Claim 1 of the '845 patent reads as follows:

> A storage-stable, sterile ephedrine ready-to-use solution composition, comprising:
>
> about 5 mg/mL of ephedrine or a pharmaceutically acceptable salt thereof;
>
> about 9 mg/mL of sodium chloride;
>
> a pH adjuster comprising acetic acid; and
>
> water,
>
> wherein the initial adjusted pH of the composition is in the range of 4.6 to 4.8;
>
> wherein the pH drift of the composition is less than 0.5 after storage for 6 months at 25° C. and 60% relative humidity; and

> wherein the composition contains about 5% or less total impurities after storage for 6 months at 25° C. and 60% relative humidity as determined by HPLC.

31. Nexus's Emerphed RTU Syringes contain a storage-stable, sterile ephedrine ready-to-use solution composition. (*See* Ex. E.)

32. Nexus's Emerphed RTU Syringes contain about 5 mg/mL of ephedrine or a pharmaceutically acceptable salt thereof. (*Id.* at § 16.)

33. Nexus's Emerphed RTU Syringes contain about 9 mg/mL of sodium chloride and water. (*Id.* at § 11.)

34. On information and belief, Nexus's Emerphed RTU Syringes contain a pH adjuster comprising acetic acid and/or satisfy this limitation under the doctrine of equivalents. (*See* Ex. D at § 11.)

35. On information and belief, Nexus's Emerphed RTU Syringes have an initial adjusted pH in the range of 4.6 to 4.8 and/or satisfy this limitation under the doctrine of equivalents.

36. On information and belief, the pH drift of Nexus's Emerphed RTU Syringes is less than 0.5 after storage for 6 months at 25°C and 60% relative humidity and/or satisfies this limitation under the doctrine of equivalents.

37. On information and belief, Nexus's Emerphed RTU Syringes contain about 5% or less total impurities after storage for 6 months at 25°C and 60% relative humidity as determined by HPLC and/or satisfies this limitation under the doctrine of equivalents.

38. Plaintiffs are entitled to a judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Nexus's Emerphed RTU Syringes, 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 Nexus's Emerphed RTU Syringes before expiration of the '845 patent by Nexus or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '845 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

39. Plaintiffs will be irreparably harmed if Nexus is not enjoined from infringing, inducing, or contributing to infringement of the '845 patent. Plaintiffs do not have an adequate remedy at law to fully compensate Plaintiffs for their damages.

40. Nexus's infringement of the '845 patent is willful, entitling Plaintiffs to enhanced damages. Nexus had knowledge of the '845 patent no later than August 17, 2021, when Nexus filed a complaint in the District of New Jersey seeking declaratory judgment that Nexus's Emerphed RTU Vials do not infringe the '845 patent. *See Nexus Pharm., Inc. v. Nevakar, Inc. et al.*, No. 21-cv-15524 (D.N.J. filed Aug. 17, 2021). Nexus therefore knew that Nexus's Emerphed RTU Syringes would infringe the '845 patent no later than August 17, 2021.

COUNT II
INFRINGEMENT OF THE '121 PATENT

41. Plaintiffs re-allege and incorporate Paragraphs 1-27 as if fully set forth herein.

42. Nexus's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Nexus's Emerphed RTU Syringes constitutes infringement of at least claim 1 of the '121 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

43. Claim 1 of the '121 patent reads as follows:

> A method of preparing a storage-stable, sterile ephedrine ready-to-use solution composition, comprising:
>
> > combining in an aqueous solution ephedrine or ephedrine sulfate and sodium chloride to a concentration of about 5 mg/mL ephedrine and about 9 mg/mL sodium chloride;

> adjusting a pH of the aqueous solution containing the ephedrine and the sodium chloride to a range of 4.6 to 4.8 to form a pH adjusted ephedrine composition;
>
> wherein the pH is adjusted with a solution containing acetic acid;
>
> wherein a pH drift of the adjusted ephedrine composition is less than 0.5 after storage for 6 months at 25° C. and 60% relative humidity; and
>
> wherein the composition contains about 5% or less total impurities after storage for 6 months at 25 C and 60% relative humidity as determined by HPLC.

44. Nexus's Emerphed RTU Syringes contain a storage-stable, sterile ephedrine ready-to-use solution composition. (*See* Ex. E.)

45. On information and belief, Nexus's Emerphed RTU Syringes are prepared by combining in an aqueous solution ephedrine or ephedrine sulfate and sodium chloride to a concentration of about 5 mg/mL ephedrine and about 9 mg/mL sodium chloride and/or satisfy this limitation under the doctrine of equivalents.

46. On information and belief, Nexus's Emerphed RTU Syringes are prepared by adjusting a pH of the aqueous solution containing the ephedrine and the sodium chloride to a range of 4.6 to 4.8 to form a pH adjusted ephedrine composition, wherein the pH is adjusted with a solution containing acetic acid and/or satisfy this limitation under the doctrine of equivalents.

47. On information and belief, Nexus's Emerphed RTU Syringes contain a storage-stable, sterile ephedrine ready-to-use solution composition wherein the pH is adjusted with a solution containing acetic acid and wherein a pH drift of the adjusted ephedrine composition is less than 0.5 after storage for 6 months at 25° C. and 60% relative humidity and/or satisfy this limitation under the doctrine of equivalents.

48. On information and belief, Nexus's Emerphed RTU Syringes contain a storage-stable, sterile ephedrine ready-to-use solution composition wherein the composition contains about 5% or less total impurities after storage for 6 months at 25 C and 60% relative humidity as determined by HPLC and/or satisfy this limitation under the doctrine of equivalents.

49. Plaintiffs are entitled to a judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Nexus's Emerphed RTU Syringes, 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 Nexus's Emerphed RTU Syringes before expiration of the '121 patent by Nexus or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '121 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

50. Plaintiffs will be irreparably harmed if Nexus is not enjoined from infringing, inducing, or contributing to infringement of the '121 patent. Plaintiffs do not have an adequate remedy at law to fully compensate Plaintiffs for their damages.

51. Nexus's infringement of the '121 patent is willful, entitling Plaintiffs to enhanced damages. Nexus first had knowledge of the '121 patent no later than about November 8, 2022, when the '121 patent issued. Nexus therefore knew that Nexus's Emerphed RTU Syringes would infringe the '121 patent no later than about November 8, 2022.

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

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment declaring that Nexus has infringed directly and indirectly one or more claims of the ’845 patent, and Nexus’s manufacture, use, sale, offer for sale and/or importation of Nexus’s Emerphed RTU Syringes infringe one or more claims of the ’845 patent;

B. A judgment permanently enjoining Nexus, its officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing the ’845 patent either directly or indirectly;

C. An award of compensatory damages to Plaintiffs for Nexus’s infringement of the ’845 patent;

D. An award of increased damages to Plaintiffs under 35 U.S.C. § 284 for Nexus’s willful and deliberate infringement of the ’845 patent;

E. A judgment declaring that Nexus has infringed directly and indirectly one or more claims of the ’121 patent, and Nexus’s manufacture, use, sale, offer for sale and/or importation of Nexus’s Emerphed RTU Syringes infringe one or more claims of the ’121 patent;

F. A judgment permanently enjoining Nexus, its officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing the ’121 patent either directly or indirectly;

G. An award of compensatory damages to Plaintiffs for Nexus’s infringement of the ’121 patent;

H. An award of increased damages to Plaintiffs under 35 U.S.C. § 284 for Nexus’s willful and deliberate infringement of the ’121 patent;

I. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Plaintiffs’ favor and awarding Plaintiffs their reasonable attorneys’ fees;

J. An award of Plaintiffs' costs and expenses for defending this action, together with pre-judgment and post-judgment interest; and

K. An award to Plaintiffs of such other and further relief as the Court may deem just and proper.

Dated: March 5, 2023

s/Christopher R. Liro

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