IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

NEXUS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 3:22-cv-00137-MGL
	)	
v.	)	
	)	**COMPLAINT**
NEPHRON SC, INC.,	)	
	)	
Defendant.	)	
	)	

Plaintiff Nexus Pharmaceuticals, Inc. ("Nexus" or "Plaintiff") by its undersigned attorneys, for its Complaint against defendant Nephron SC, Inc. ("Nephron" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendant's submission of Abbreviated New Drug Application ("ANDA") No. 216313 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of EMERPHED® (ephedrine sulfate) 50mg/10ml (5 mg/mL) IV solution prior to the expiration of U.S. Patent No. 11,090,278 ("the '278 patent" or "the patent in suit"), attached hereto as Exhibit A.

PARTIES

2. Nexus is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 400 Knightsbridge Parkway, Lincolnshire, Illinois.

3. Nexus is the holder of New Drug Application No. 213407 for EMERPHED®, (ephedrine sulfate) 50mg/10ml (5 mg/mL) IV solution.

4. Nexus is the owner and assignee of the '278 patent.

5. Upon information and belief, Nephron is a corporation organized and existing under the laws of the State of South Carolina, having a manufacturing facility and principal place of business at 4500 12th St Extension, West Columbia, SC 29172.

6. Upon information and belief, Nephron is a pharmaceutical manufacturer who specializes in "generic respiratory medication manufacturing" and "offers drug compounding for 503B outsourcing through its sterile, cGMP facility."[1]

7. Upon information and belief, Nephron derives substantial revenue from the manufacture, compounding, and/or sale of generic pharmaceutical products in the United States and South Carolina.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

[1] About, https://www.nephronpharm.com/about (last visited January 10, 2022).

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Nephron is organized and existing under the laws of the State of South Carolina and therefore resides there for purposes of venue.

10. Based on the facts and causes alleged herein, including infringement under 35 U.S.C. § 271(e)(2) by Nephron's ANDA and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Nephron.

11. On information and belief, Nephron is a company organized and existing under the laws of the State of South Carolina, has registered to do business in the State of South Carolina, and has appointed a registered agent in South Carolina to accept service of process. Nephron has thus consented to personal jurisdiction in South Carolina.

12. On information and belief, Nephron has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 216313 in the United States, including in South Carolina.

13. On information and belief, if Nephron receives approval for ANDA No. 216313, Nephron will manufacture the generic product described in ANDA No. 216313 in South Carolina and will market, distribute, offer for sale, and/or sell the generic product described in ANDA No. 216313 in the United States, including in South Carolina, and will derive substantial revenue from the use or consumption of the generic product described in ANDA No. 216313 in the State of South Carolina. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

14. On information and belief, if ANDA No. 216313 is approved, the generic product described in ANDA No. 216313 would, among other things, be manufactured, marketed,

distributed, offered for sale, and/or sold in South Carolina, prescribed by physicians practicing in South Carolina, dispensed by pharmacies located within South Carolina, and/or used by patients in South Carolina, all of which would have a substantial effect on South Carolina.

15. Nephron has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of South Carolina by having filed suit in this jurisdiction. *See, e.g.*, *Nephron Pharmaceuticals Corp. et al. v. Parker*, Case No. 3:21-cv-01278-JMC (April 29, 2021)*; Nephron Pharmaceuticals Inc. v. Nephron Sterile Compounding Center LLC et al.,* Case No. 3:20-cv-02956-MGL (D.S.C. August 14, 2020); *Nephron Pharmaceuticals Corporation. et al. v. V. Lane*, Case No. 3:20-cv-04356-MGL-PJG (D.S.C. December 16, 2020).

BACKGROUND

16. EMERPHED® is sold and marketed under New Drug Application No. 213407, which was approved by the FDA on April 21, 2020.

17. EMERPHED® is the first and only FDA-approved ready to use ephedrine injection and is supplied as a single-use 10mL vial containing 50mg ephedrine sulfate.

18. Ephedrine, the active ingredient in EMERPHED®, is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent. EMERPHED® is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

19. The ’278 patent, entitled “Compositions comprising ephedrine or an ephedrine salt and methods of making and using same” was duly and legally issued on August 17, 2021.

20. The ’278 patent has been listed in connection with EMERPHED® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

21. As indicated in the Orange Book, the patent expiration date for the '278 patent is May 16, 2040.

22. Upon information and belief, Nephron prepared ANDA No. 216313.

23. By letter dated November 30, 2021 ("the Notice Letter"), Nephron notified Nexus pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Nephron had submitted to the FDA ANDA No. 216313, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic Ephedrine Sulfate Injection USP, 50mg/10mL (5 mg/mL) single dose vials ("Nephron's ANDA Product") prior to the expiration of the '278 patent.

24. Upon information and belief, Nephron submitted ANDA No. 216313 to the FDA, which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification") asserting that the '278 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Nephron's ANDA Product, or alternatively, that these patents are invalid.

25. Upon information and belief, Nephron's ANDA Product is a drug product that is a generic version of EMERPHED®, (ephedrine sulfate) 50mg/10ml (5 mg/mL) IV solution, as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

26. In the Notice Letter, Nephron disclosed that the active ingredient of Nephron's ANDA product is ephedrine sulfate.

27. Upon information and belief, Nephron's ANDA product is a ready to use pre-mixed composition to be stored at the same or equivalent conditions as EMERPHED®.

28. Upon information and belief, Nephron's ANDA product contains ephedrine sulfate, sodium chloride, and water in the same or equivalent amounts as EMERPHED®. Upon information and belief, Nephron's ANDA product does not contain a preservative.

29. Upon information and belief, Nephron's ANDA product will feature the same or equivalent chemical properties as EMERPHED®.

30. Upon information and belief, Nephron's ANDA product will be manufactured using the same or equivalent methods as EMERPHED®.

31. Upon information and belief, Nephron's ANDA product will use an equivalent container to EMERPHED®.

32. Upon information and belief, Nephron's ANDA product will be sterilized in an equivalent method to EMERPHED®.

33. Upon information and belief, Nephron's ANDA product is to be stored at the same or equivalent conditions as EMERPHED®.

34. In the Notice Letter, Nephron disclosed that the Nephron ANDA Product seeks approval for the indication of treatment of clinically important hypotension occurring in the setting of anesthesia.

35. Upon information and belief, the proposed labeling for Nephron's ANDA product recommends, instructs, and/or promotes administration of Nephron's ANDA product to patients having hypotension or an elevated risk of developing hypotension.

36. Upon information and belief, the proposed labeling for Nephron's ANDA product recommends, instructs, and/or promotes administration to patients by drawing the composition into a syringe and injecting the composition into a patient using the syringe.

37. Any final approval of Nephron's ANDA shall be effective no earlier than May 30, 2024. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT I – INFRINGEMENT OF
U.S. PATENT NO. 11,090,278 UNDER 35 USC §271(e)(2)

38. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

39. Nephron's submission of ANDA No. 216313 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Nephron's ANDA Product prior to the expiration of the '278 patent was an act of infringement of the '278 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Nephron will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Nephron's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 216313.

41. Upon information and belief, the use of Nephron's ANDA Product in accordance with and as directed by Nephron's proposed labeling for that product would infringe one or more claims of the '278 patent, either literally or under the doctrine of equivalents.

42. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Nephron's ANDA Product would induce or contribute to infringement of one or more claims of the '278 patent, either literally or under the doctrine of equivalents.

43. Upon information and belief, Nephron plans and intends to, and will, actively induce infringement of the '278 patent when ANDA No. 216313 is approved, and plans and intends to, and will, do so after approval.

44. Upon information and belief, Nephron knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’278 patent, either literally or under the doctrine of equivalents, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

45. Upon information and belief, Nephron plans and intends to, and will, contribute to infringement of the ’278 patent after approval of ANDA No. 216313.

46. The foregoing actions by Nephron constitute and/or will constitute infringement of the ’278 patent, active inducement of infringement of the ’278 patent, and contribution to the infringement by others of the ’278 patent.

47. Upon information and belief, Nephron has acted with full knowledge of the ’278 patent and without a reasonable basis for believing that it would not be liable for infringing the ’278 patent, actively inducing infringement of the ’278 patent, and contributing to the infringement by others of the ’278 patent.

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

49. Unless Nephron is enjoined from infringing the ’278 patent, actively inducing infringement of the ’278 patent, and contributing to the infringement by others of the ’278 patent, Nexus will suffer irreparable injury. Nexus has no adequate remedy at law.

WHEREFORE, Nexus requests the following relief:

a. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), that Nephron has infringed the ’278 patent by submitting to the FDA ANDA No. 216313 with a paragraph IV certification for

the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Nephron's ANDA Product before the expiration of the '278 patent;

b. A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Nephron's ANDA Product before the expiration of the '278 patent (including any regulatory extension), will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '278 patent;

c. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 216313 shall be no earlier than the date on which the '278 patent expires, inclusive of any extension or additional period of exclusivity;

d. A judgment that the '278 patent is valid and enforceable;

e. An order pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval for Nephron to make, use, offer for sale, sell, market, distribute, or import Nephron's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '278 patent, be no earlier than the expiration date of the '278 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

f. An order for preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Nephron, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Nephron's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '278 patent, or the inducement of or the contribution to any of the foregoing,

prior to the expiration of the ’278 patent, inclusive of any extension or additional period of exclusivity;

g. An award, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, of damages or other monetary relief to compensate Nexus if Nephron engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Nephron’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’278 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’278 patent, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

h. A judgment pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284 declaring that Nephron’s infringement of the ’278 patent is willful and awarding Nexus enhanced damages if Nephron commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Nephron’s ANDA, prior to the expiration of the ’278 patent (including any regulatory extension);

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

j. Such further and other relief as this Court may deem just and proper.

Dated: January 14, 2022

/s/ Tasneem A. Dharamsi

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