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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. NEVAKAR, INC., NEVAKAR INJECTABLES, INC., PAR STERILE PRODUCTS, LLC, PAR PHARMACEUTICAL, INC., ENDO VENTURES LTD., AND ENDO INTERNATIONAL PLC, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Nexus Pharmaceuticals, Inc. ("Nexus"), by and through its undersigned attorneys, for its Complaint against Defendants Nevakar, Inc. ("Nevakar"), Nevakar Injectables,

Inc. ("Nevakar Injectables"), Par Sterile Products, LLC ("Par Sterile"), Par Pharmaceutical, Inc. ("Par"), Endo Ventures Limited ("Endo"), and Endo International plc ("EIP") (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 No. 11,426,369 ("the '369 patent" or "the patent-in-suit") based upon a real, immediate, substantial, and justiciable controversy between the parties.

2. The act of infringement relates 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 an ephedrine sulfate 25 mg/5 mL (5 mg/mL) solution in a 5 mL prefilled syringe before expiration of the '369 patent.

THE PARTIES

3. 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 60069.

4. Nexus is the holder of New Drug Application ("NDA") No. 213407 for EMERPHED®, (ephedrine sulfate) 50mg/10ml (5 mg/mL) IV solution. EMERPHED® was the first FDA-approved "ready to use" formulation with a 5 mg/mL concentration.

5. Nexus applied for and obtained patents related to its inventions for the ready to use 5 mg/mL concentration, including the '369 patent. Nexus is the owner and assignee of the '369 patent.

6. On information and belief, Nevakar 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. On information and belief, Nevakar is a fully integrated, privately held, late-stage biopharmaceutical company with an extensive portfolio of products in the sterile-injection and ophthalmic areas.

7. On information and belief, 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. On information and belief, Nevakar Injectables was formed in 2021 as a wholly-owned subsidiary of Nevakar and is developing a broad portfolio of sterile-injection products for use in hospitals and ambulatory care settings, such as medical offices, clinics, and ambulatory surgery centers.

8. On information and belief, Par Sterile is a limited liability company organized and existing under the laws of Delaware, with a place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile is a wholly-owned subsidiary, directly or indirectly, of EIP.

9. On information and belief, Par is a corporation organized and existing under the laws of Delaware, with a place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par is a wholly-owned subsidiary, directly or indirectly, of EIP.

10. On information and belief, Endo is a company organized and existing under the laws of Ireland, with a place of business at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland. On information and belief, Endo has regular and established places of business in Cranbury, New Jersey and East Windsor, New Jersey. Endo is a wholly-owned subsidiary, directly or indirectly, of EIP.

11. On information and belief, EIP is a company organized and existing under the laws of Ireland, with a place of business at First Floor, Minerva House, Simmonscourt Road,

Ballsbridge, Dublin 4, Ireland. On information and belief, EIP has regular and established places of business in Cranbury, New Jersey and East Windsor, New Jersey.

JURISDICTION AND VENUE

12. 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.*

13. 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 patent-in-suit as detailed below.

14. This Court has personal jurisdiction over Defendants because Defendants' contacts within this judicial district are continuous and systematic. On information and belief, Nevakar, Nevakar Injectables, Par Sterile, Par, Endo, and EIP, 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.

15. This Court has personal jurisdiction over Par because of, *inter alia*, its continuous and systematic contacts with the State of New Jersey and corporate entities within this judicial district, including as a subsidiary, agent, and/or alter-ego of Endo and/or EIP, its previous submission to the jurisdiction of this judicial district, and its substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district including through, directly or indirectly, EIP.

16. This Court has personal jurisdiction over Par Sterile because of, *inter alia*, its continuous and systematic contacts with the State of New Jersey and corporate entities within this judicial district, including as a subsidiary, agent, and/or alter-ego of Endo and/or EIP, its previous submission to the jurisdiction of this judicial district, and its substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district including through, directly or indirectly, EIP.

17. This Court has personal jurisdiction over Endo because of, *inter alia*, Endo's continuous and systematic contacts with corporate entities within this judicial district, and Endo's 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.

18. This Court has personal jurisdiction over EIP because of, *inter alia*, EIP's continuous and systematic contacts with corporate entities within this judicial district, and its 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 through various wholly-owned subsidiaries including Endo, Par, and Par Sterile.

19. This Court has personal jurisdiction over Nevakar because Nevakar has a principal place of business at 1019 US Highway 202 #206, Bridgewater, New Jersey 08807.

20. This Court has personal jurisdiction over Nevakar Injectables because Nevakar Injectables has a principal place of business at 1019 US Highway 202 #206, Bridgewater, New Jersey 08807.

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

22. On information and belief, Nevakar is registered with the State of New Jersey's Department of the Treasury, Division of Revenue as "Nevakar Inc.," registration number 0450656580, registered on January 23, 2018.

23. On information and belief, Nevakar Injectables is registered with the State of New Jersey's Department of the Treasury, Division of Revenue as "Nevakar Injectables Inc.," registration number 0450656580, registered on May 28, 2021.

24. On information and belief, Nevakar and Nevakar Injectables purposefully have conducted and continue to conduct business in this judicial district, and this judicial district is a destination of Nevakar's and Nevakar Injectable's pharmaceutical products.

25. On information and belief, Nevakar Injectables, Endo, and Par Sterile have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by filing counterclaims in this jurisdiction. *See, e.g., Nexus Pharmaceuticals, Inc. v. Endo Ventures Limited et al.*, Case No. 1:21-cv-15524-RMB-KMW (D.N.J.) (Dkt. No. 44) (filed Oct. 5, 2021).

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

27. On information and belief, Par Sterile is registered with the State of New Jersey's Department of the Treasury, Division of Revenue as "Par Sterile Products, LLC," registration number 0600303655, registered on July 9, 2007.

28. On information and belief, Par is registered with the State of New Jersey's Department of the Treasury, Division of Revenue as "Par Pharmaceutical, Inc.," registration number 0450710552, registered on October 5, 2021.

29. On information and belief, Par Sterile has previously availed itself of the jurisdiction of this Court by filing complaints in this judicial district. *See, e.g., Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals Inc.*, No. 20-18319 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Amneal EU, Ltd. et al.*, No. 20-18322 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 20-18328 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Aurobindo Pharma U.S.A., Inc. et al.*, No. 20-18334 (D.N.J.).

30. On information and belief, Par Sterile has previously availed itself of the jurisdiction of this Court by filing motions to transfer to this judicial district. *See, e.g., Eagle Pharmaceuticals, Inc. v. Par Sterile Products, LLC et al.*, No. 18-11923 (D.N.J.).

31. On information and belief, Par has previously availed itself of the jurisdiction of this Court by filing complaints in this judicial district. *See, e.g., Par Pharmaceutical, Inc. et al. v. Cipla Limited et al.*, No. 22-02814 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals Inc.*, No. 20-18319 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Amneal EU, Ltd. et al.*, No. 20-18322 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 20-18328 (D.N.J.); *Par Pharmaceutical, Inc. et al. v. Aurobindo Pharma U.S.A., Inc. et al.*, No. 20-18334 (D.N.J.); *Par Pharmaceutical, Inc. v. Merck Sharp & Dohme Corp.*, No. 19-04432 (D.N.J.).

32. On information and belief, Par has previously been sued in this judicial district and has not challenged personal jurisdiction and venue. *See, e.g., Indivior Inc. et al. v. Par Pharmaceutical Inc. et al.*, No. 17-07997 (D.N.J.); *Celgene Corporation v. Par Pharmaceutical,*

Inc. et al., No. 17-03159 (D.N.J.); *Supernus Pharmaceuticals, Inc. v. Par Pharmaceutical Companies, Inc.*, No. 15-00326 (D.N.J.); *Helsinn Healthcare S.A. v. Par Pharmaceutical Companies Inc.*, No. 15-02078 (D.N.J.).

33. On information and belief, Par holds itself out as a wholly-owned subsidiary of EIP.

34. On information and belief, Par Sterile holds itself out as a wholly-owned subsidiary of EIP.

35. On information and belief, Par and Par Sterile hold themselves out to the public as "employ[ing] highly talented professionals in [their] US facilities in . . . Cranbury, New Jersey." *See, e.g.*, https://www.parpharm.com/facilities/.

36. On information and belief, Par and Par Sterile have a "network of manufacturing facilities . . . located in Cranbury," New Jersey. *See, e.g.*, https://www.parpharm.com/facilities/.

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

38. On information and belief, Endo is registered with the State of New Jersey's Department of Treasury, Division of Revenue through its wholly-owned subsidiary Endo Pharmaceuticals Inc. as "Endo Pharmaceuticals Inc.," registration number 0100721596, registered on October 2, 1997.

39. On information and belief, Endo holds itself out as a wholly-owned subsidiary of EIP.

40. On information and belief, Par, Par Sterile, Endo, and EIP hold themselves out to the public as having a physical location in Cranbury, New Jersey. *See, e.g.*, https://www.parpharm.com/facilities/.

41. On information and belief, Endo and/or EIP operates and maintains a regular and established place of business located at 7 Clarke Drive, Cranbury, New Jersey 08512.

42. On information and belief, Par, Par Sterile, Endo, and EIP 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.

43. On information and belief, Par acts at the direction, and for the benefit, of Endo and EIP, and is controlled and/or dominated by Endo and EIP.

44. On information and belief, Par Sterile acts at the direction, and for the benefit, of Endo and EIP, and is controlled and/or dominated by Endo and EIP.

45. On information and belief, EIP, either directly or indirectly through its wholly-owned subsidiaries, is in the business of making and selling pharmaceutical products, which it distributes, markets, and/or sells in New Jersey and throughout the United States.

46. On information and belief, Par, Par Sterile, Endo, and EIP hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing pharmaceutical products in the United States.

47. 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 from the Federal Food and Drug Administration ("FDA") for an ephedrine sulfate 25 mg/5 mL (5 mg/mL) solution in a 5 mL prefilled syringe under NDA No. 213994 ("Defendants' Prefilled Syringe Product"), and have commenced and/or will imminently commence manufacturing, marketing, and sale of Defendants' Prefilled Syringe 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.

48. For the product described in NDA No. 213994, 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, Defendants' Prefilled Syringe Product for commercial distribution from facilities in New Jersey owned by Par, Par Sterile and Endo, or by their shared parent corporation, EIP.

49. EIP controls and directs the actions of Par, Par Sterile and Endo, including the marketing, sale, and distribution of pharmaceutical products from and through its facilities located in New Jersey and to companies and customers located in New Jersey. Upon information and belief, EIP is a holding company that conducts business through its operating subsidiaries, including Par, Par Sterile and Endo. EIP will direct and control the activities of its agents Par, Par Sterile and Endo to sell and distribute pharmaceutical products throughout the United States and in New Jersey, including Defendants' Prefilled Syringe Product that is at issue in this case.

50. 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.

51. With respect to Nevakar and Nevakar Injectables, venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, upon information and belief, Nevakar and Nevakar Injectables have a regular and established place of business in this judicial district,

and manufacture or direct and control the manufacture of, or will manufacture or direct and control the manufacture of, Defendants' Prefilled Syringe Product, in concert with Par, Par Sterile, Endo and EIP, from a place that is located in this judicial district.

52. With respect to Par, Par Sterile, Endo, and EIP, venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, upon information and belief, Par, Par Sterile, and Endo have a regular and established place of business in this judicial district, and manufacture or direct and control the manufacture of, or will manufacture or direct and control the manufacture of, Defendants' Prefilled Syringe Product, in concert with Nevakar and/or Nevakar Injectables, from a place that is located in this judicial district, and distribute the product at issue from a place of business owned by their shared parent company EIP that is located in this judicial district.

53. In addition, with respect to Endo and EIP, venue is proper in this district pursuant to 28 U.S.C. § 1391(c)(3) as both are foreign corporations.

NEXUS'S EMERPHED® PRODUCT AND '369 PATENT

54. EMERPHED® is sold and marketed under NDA No. 213407, which was approved by the FDA in April 2020.

55. 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.

56. The '369 patent, entitled "Compositions Comprising Ephedrine Or An Ephedrine Salt And Methods Of Making And Using Same," was duly and legally issued on August 30, 2022. A true and correct copy of the '369 patent is attached hereto as Exhibit A.

57. The ’369 patent stems from U.S. Application No. 17/556,904 (“the ’904 application”), filed on December 20, 2011, which claims priority to U.S. Application No. 17/381,770, filed on July 21, 2021, which in turn claims priority to U.S. Application No. 16/876,020, filed on May 16, 2020 (now U.S. Patent No. 11,090,278), and ultimately claims priority to U.S. Provisional Application No. 62/849,125, filed on May 16, 2019.

58. The ’369 patent claims are directed to a shelf-stable, ready to use ephedrine sulfate composition.

59. The ’369 patent is valid and duly issued, and will not expire until at least May 16, 2040.

DEFENDANTS’ PREFILLED SYRINGE PRODUCT AND INFRINGING CONDUCT

60. On information and belief, Nevakar and Endo entered into a Development, License, and Commercialization Agreement in or around 2018 (“the 2018 Agreement”) for Defendants to develop, manufacture, have manufactured, distribute, use, market, have marketed, sell, have sold, import, and/or otherwise commercialize, *inter alia*, Defendants’ Prefilled Syringe Product.

61. On information and belief, in connection with the 2018 Agreement, Defendants have engaged in a coordinated scheme to manufacture and sell Defendants’ Prefilled Syringe Product.

62. Based upon FDA’s electronic records, Endo is the current holder of approved NDA No. 213994. On information and belief, ownership of NDA No. 213994 was transferred from Nevakar to Endo and its affiliates on or about October 29, 2020, and Endo has made additional submissions to the FDA regarding the products described in NDA No. 213994.

63. On information and belief, one or more of the Defendants supplemented NDA No. 213994 to seek approval for an ephedrine sulfate prefilled syringe presentation. According to

FDA's online database, on or about April 22, 2022, the FDA approved this NDA supplement, which describes Defendants' Prefilled Syringe Product.

64. According to the FDA-approved label for NDA No. 213994, as revised in April 2022, Defendants' Prefilled Syringe Product is a "5 mL single-dose prefilled syringe; (25 mg/5 mL, equivalent to 19 mg ephedrine base)." Exhibit B at 1.

65. The FDA-approved April 2022 label for Defendants' Prefilled Syringe Product instructs that suspected adverse reactions should be reported to "Par Pharmaceutical." *Id.* "Par Pharmaceutical" is also listed on the FDA-approved April 2022 label as the distributor. *Id*. at 12.

66. Publicly available information, including the FDA-approved product label for Defendants' Prefilled Syringe Product, describe Defendants' Prefilled Syringe Product, and how it is manufactured. *See generally id*.

67. Specifically, on information and belief, Defendants' Prefilled Syringe Product is a sterile, shelf-stable, ready-to-use ephedrine sulfate composition presented in a sealed 5 mL single-dose prefilled syringe containing 5 mg/mL ephedrine sulfate, 9 mg/mL sodium chloride, water with a pH of between 4.5 and 7, and no preservative. *See generally* Exhibit B. Reported information including on the Defendants' April 2022 product label shows that a method is used to make a ready-to-use formulation that is shelf-stable and comprises 5 mg/mL ephedrine sulfate. *Id*. at 2, 11-12. Reported information including on the Defendants' April 2022 product label shows there are no preservatives contained in the formulation. *Id*. at 12. On information and belief, Defendants filter their product through a membrane to obtain a filtered batch solution. *Id.* at 2. On information and belief, Defendants' Prefilled Syringe Product is contained in sanitized and sterilized sealed containers. *Id.* at 10. On information and belief, Defendants' Prefilled Syringe

Product is shelf-stable for 6 and/or 12 months, and is stable at both ambient and accelerated conditions. *Id.* at 12.

68. On information and belief, Defendants collaborated in the research, development, preparation, and filing of NDA No. 213994 for ephedrine sulfate injection, 5 mg/mL, and further collaborated in the plans and preparation for the commercial manufacture of Defendants' Prefilled Syringe Product in the United States.

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

70. Nevakar, in concert with the other Defendants, publicly reported from Bridgewater, New Jersey, that: "[Defendants' Prefilled Syringe Product] is an ephedrine formulation prediluted to a 5mg/mL concentration and supplied in a ready-to use 5mL PFS. It will be marketed and sold in the U.S. by the Par Sterile Products ('Par') business of Endo International plc ('Endo')." *See* Apr. 28, 2022 Press Release (Exhibit C), available at https://nevakarinjectables.com/news/nevakar-injectables-receives-u-s-fda-approval-of-ready-to-use-ephedrine-injection-in-a-prefilled-syringe%ef%bf%bc/.

71. Defendants' April 28, 2022 press release reports that: "With the added approval of the ephedrine prefilled syringe, Nevakar and Endo aim to offer a portfolio of ephedrine products to health care professionals treating patients in the surgical setting." *See id.*

72. On information and belief, Par Sterile's, Par's, Endo's and EIP's efforts to commercialize the Defendants' Prefilled Syringe Product are constant and all-encompassing.

73. On information and belief, Nevakar and Nevakar Injectables are unwavering in their commitment to commercialize Defendants' Prefilled Syringe Product.

74. On information and belief, Defendants have commercial plans for an upcoming launch of Defendants' Prefilled Syringe Product.

75. 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, Defendants' Prefilled Syringe Product, so that the product can be offered for sale and sold in the United States and in this District.

76. On information and belief, Defendants intend that, following manufacture of Defendants' Prefilled Syringe Product, one or more of the Defendants will sell, distribute, and/or direct the sale and distribution of, the prefilled syringe product under NDA No. 213994 that is, or will be, manufactured by or at the direction of Defendants.

77. On information and belief, Defendants have begun a concerted effort to offer for sale and sell their manufactured Prefilled Syringe Product before the expiration of the '369 patent asserted in this action.

78. As set forth in Counts I and II below, the actual and/or imminent manufacture of Defendants' Prefilled Syringe Product infringes one or more claims of the '369 patent.

79. On information and belief, Defendants were aware of and tracked Nexus's '904 application through prosecution at the United States Patent and Trademark Office.

80. On information and belief, Defendants were aware of and had knowledge of the allowed claims that have now issued as part of the '369 patent, and Defendants have been aware of Nexus's issued '369 patent since August 30, 2022. Despite that knowledge of the '369 patent, Defendants have indicated no intent to stop their actually occurring or imminent infringing activity described above.

COUNT I
INFRINGEMENT OF THE '369 PATENT

81. Nexus incorporates and realleges Paragraphs 1-80 above.

82. On information and belief, Defendants manufacture, or direct and control the manufacture of, Defendants' Prefilled Syringe Product for sale in the United States, and these acts directly and/or indirectly infringe one or more claims of the '369 patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

83. Individually and collectively, Defendants' manufacture, or direction and control of the manufacture, of Defendants' Prefilled Syringe Product constitutes infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

84. On information and belief, the manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions constitutes direct infringement of the '369 patent.

85. On information and belief, the manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions are inducing infringement of the '369 patent.

86. On information and belief, the manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions are contributing to the infringement of the '369 patent.

87. The '369 patent has nine claims directed to methods for making a shelf-stable, ready-to-use ephedrine sulfate composition.

88. As one example, independent claim 1 of the '369 patent is directed to:

> A method of making a shelf-stable, ready-to-use ephedrine sulfate composition, the method comprising:

> combining ephedrine sulfate, sodium chloride or dextrose, and water to form a batch solution comprising an initial ephedrine sulfate level of 5 mg/mL, 9 mg/mL sodium chloride or 5% dextrose, and no preservative;
>
> optionally contacting the batch solution with an acid or a base to obtain an initial pH level of the solution of 4.5 to 7;
>
> filtering the batch solution through a membrane filter to obtain a filtered batch solution;
>
> sanitizing one or more containers;
>
> placing not more than 20 mL of the filtered batch solution into one of the one or more sanitized containers to obtain one or more filled containers;
>
> sealing each filled container to obtain sealed containers including a shelf-stable, ready-to-use ephedrine sulfate composition; and
>
> maintaining a pH level of the shelf-stable, ready-to-use ephedrine sulfate composition in the sealed containers that is within 0.5 pH units of the initial pH level during storage at 25° C. and 60% relative humidity for at least 12 months or during storage at 40° C. and 75% relative humidity for at least 6 months.

89. 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 of Defendants' Prefilled Syringe Product meets each and every limitation of claim 1 of the '369 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 '369 patent because each step of the claims is performed by and/or attributable to Defendants. Upon information and belief, Defendants indirectly infringe the '369 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 ’369 patent.

90. On information and belief, Defendants have no reasonable basis for believing that Defendants’ Prefilled Syringe Product will not infringe one or more valid claims of the ’369 patent and no reasonable basis for believing that the infringed claims are invalid.

91. Defendants’ manufacture of Defendants’ Prefilled Syringe Product constitutes willful infringement.

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

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

94. Nexus is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, or selling Defendants’ Prefilled Syringe Product in the United States before expiration of the ’369 patent.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’369 PATENT

95. Nexus incorporates and realleges Paragraphs 1-94 above.

96. 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.

97. To the extent that Defendants contend that there has been no manufacture of Defendants’ Prefilled Syringe Product at this time, there is still an actual case or controversy such that the Court may entertain Nexus’s 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.

98. Upon information and belief, FDA's approval of Defendants' Prefilled Syringe Product, coupled with Defendants' commercial activities in support of the imminent manufacture, importation and/or launch of Defendants' Prefilled Syringe Product, including at least: (i) Defendants' application to the FDA for permission to market their Prefilled Syringe Product; (ii) Defendants' public announcement of the FDA's approval; (iii) and Defendants' commitment to commercializing Defendants' Prefilled Syringe 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 '369 patent before the patent's expiration in violation of 35 U.S.C. § 271(a), (b), (c), and/or (g).

99. On information and belief, Defendants have engaged in and will continue to engage in substantial activities in preparation to manufacture and market Defendants' Prefilled Syringe Product in the United States.

100. On information and belief, Defendants will imminently manufacture, or direct and control the imminent manufacture of, Defendants' Prefilled Syringe Product for sale in the United States, and these acts directly and/or indirectly will infringe one or more claims of the '369 patent literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

101. Individually and collectively, Defendants' imminent manufacture, or direction and control of the manufacture, of Defendants' Prefilled Syringe Product will constitute infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

102. On information and belief, the imminent manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions will constitute direct infringement of the '369 patent.

103. On information and belief, the imminent manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions will constitute induced infringement of the '369 patent.

104. On information and belief, the imminent manufacture of Defendants' Prefilled Syringe Product is covered by the claims of the '369 patent, and one or more of Defendants' actions will constitute contributory infringement of the '369 patent.

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

106. On information and belief, Defendants have no reasonable basis for believing that Defendants' Prefilled Syringe Product will not infringe one or more valid claims of the '369 patent and no reasonable basis for believing that those claims are invalid.

107. Defendants' imminent manufacture of Defendants' Prefilled Syringe Product will constitute willful infringement.

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

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

110. Nexus is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, or selling Defendants' Prefilled Syringe Product in the United States before expiration of the '369 patent.

PRAYER FOR RELIEF

111. At this time Nexus seeks relief only with respect to infringing conduct that occurred or will occur on or after August 30, 2022.

112. Nexus did not and could not have commenced this action seeking the relief requested below related to infringement of the '369 patent prior to August 30, 2022.

WHEREFORE, Nexus 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 Defendants' Prefilled Syringe Product on or after August 30, 2022, and before the expiration of the '369 patent (including any regulatory extension), has infringed the '369 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 Defendants' Prefilled Syringe Product will infringe the '369 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g);

C. A judgment that the '369 patent is valid and enforceable;

D. An order for preliminary and permanent injunction for Defendants' unlawful conduct;

E. An award, pursuant to 35 U.S.C. § 284, of damages or other monetary relief to compensate Nexus for Defendants' engagement in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' Prefilled Syringe Product, or any product the making, using, offering for sale, sale, marketing, distribution, and/or importation of which infringes the '369 patent;

F. Awarding Nexus enhanced damages;

G. 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

H. Such other and further relief to Nexus as this Court may deem just and proper.

Dated: September 23, 2022

Respectfully submitted,

/s/ Justin T. Quinn

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