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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

NEXUS PHARMACEUTICALS, INC. Plaintiff, v. NEVAKAR, INC., PAR PHARMACEUTICALS CO., INC., ENDO VENTURES LTD.; ENDO INTERNATIONAL PLC Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiff Nexus Pharmaceuticals, Inc. ("Nexus"), by and through its undersigned attorneys, for its complaint against Defendants Nevakar, Inc. ("Nevakar"), Par Pharmaceuticals Co., Inc. ("Par"), Endo Ventures Ltd. ("Endo"), and Endo International plc ("EIP") (collectively "Defendants"), alleges as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States,

Title 35, United States Code Section 271, regarding a ready-to-use ephedrine sulfate injection product Defendants intend to manufacture and sell in the United States that will infringe Nexus's U.S. Patent No. 11,090,278 ("the '278 patent").

2. This is also an action for declaratory judgment of patent non-infringement under 28 U.S.C. § 2201(a) that the manufacture, use, sale, and offer for sale of Nexus's EMERPHED® ephedrine sulfate injection product does not and will not infringe any valid claim of Nevakar's U.S. Patent No. 10,869,845 ("the '845 patent").

THE PARTIES

3. Nexus is a corporation organized and existing under the laws of the State of Illinois. Its principal place of business is located at 400 Knightsbridge Parkway, Lincolnshire, Illinois 60069.

4. On information and belief, Nevakar is a corporation organized and existing under the laws of the state of Delaware with a place of business at 1019 US Highway 202-206, Building K, NJ Center of Excellence, Bridgewater, NJ 08807.

5. On information and belief, Par is a corporation organized and existing under the laws of Delaware with a place of business at 1 Ram Ridge Rd., Chestnut Ridge, New York 10977. Par is a wholly-owned subsidiary, directly or indirectly, of EIP.

6. On information and belief, Endo is a company organized and existing under the laws of Ireland. Endo is a wholly-owned subsidiary, directly or indirectly, of EIP.

7. On information and belief, EIP is a company organized and existing under the laws of Ireland, having 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

8. This action for patent infringement arises under 35 U.S.C. § 1 et seq. generally and 35 U.S.C. § 271 specifically.

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

10. This Court has personal jurisdiction over Defendants because Defendants' contacts within this Judicial District are continuous and systematic. On information and belief, Nevakar, Par, Endo, and EIP, individually and collectively acting in concert and cooperatively, develop, manufacture, seek approval for, and sell FDA-approved pharmaceutical drugs that are regularly marketed, distributed, and sold in New Jersey and throughout the United States.

11. 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.

12. 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.

13. 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 and Par.

14. On information and belief, Nevakar directly or indirectly manufactures, markets, and sells drug products throughout the United States and in this judicial district.

15. 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 0101047106, registered on January 23, 2018.

16. On information and belief, Par directly or indirectly manufactures, markets, and sells drug products throughout the United States and in this judicial district.

17. On information and belief, Par is registered with the State of New Jersey's Department of Treasury, Division of Revenue as a "Par Pharmaceutical Companies, Inc.," registration number 0100946477, registered on May 27, 2005. On information and belief, Par also maintains a registered agent in the State of New Jersey.

18. On information and belief, Par has 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.).

19. 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.).

20. On information and belief, EIP acquired Par Pharmaceutical Holdings, Inc. on September 25, 2015, and following the closing Par Pharmaceutical Holdings, Inc. changed its name to Par Pharmaceutical Companies, Inc.

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

22. 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.

23. 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.

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

25. On information and belief, Par, 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/ (last visited Aug. 17, 2021).

26. 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.

27. On information and belief, Par, 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.

28. 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.

29. 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.

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

31. 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 for an ephedrine sulfate injection product under New Drug Application ("NDA") No. 213994, and will commence manufacturing, marketing, and sale of the product covered by NDA No. 213994 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 District.

32. For the product described in NDA No. 213994, Nevakar filed NDA No. 213994 and developed and on information and belief will manufacture the product for commercial distribution at its facilities in New Jersey, and Par and Endo will purchase such products from Nevakar in New Jersey for manufacturing and/or distribution from facilities in New Jersey owned by Par and Endo or by their shared parent corporation, EIP. EIP controls and directs the actions of Par 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. In fact, EIP's 2020 10-K filed with the U.S. Security Exchange Commission at page 1 says "Endo International plc is a holding company that conducts business through its operating subsidiaries." EIP will direct and control the activities of its agents Par and Endo to sell and distribute pharmaceutical products throughout the United States and in New Jersey, including the ephedrine sulfate products that are at issue in this case.

33. 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.

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

35. With respect to Par, 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 and Endo have a regular and established place of business in this Judicial District, and/or will distribute the product at issue from a place of business owned by their shared parent company EIP that is located in this Judicial District.

36. 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

37. It is a critical medical practice to administer anesthesia to patients undergoing surgical procedures. One side effect of many anesthesia drugs is hypotension, or lowering of blood pressure. If the blood pressure drops too far, then this can risk complications during

surgery, including death.

38. The FDA has approved Nexus's branded drug ephedrine sulfate for use in surgical settings to raise blood pressure when a patient under anesthesia begins experiencing hypotension severe enough to affect the patient's health. However, until 2020 other FDA-approved forms of ephedrine sulfate were provided in a concentrated form of 50 mg/mL, and required further dilution to be ready to use. In other words, other FDA-approved products required the hospital pharmacy, nursing staff, or doctors to dilute the vial with saline or another liquid down to the appropriate concentration of 5 mg/mL before the drug could be administered to a patient. The requirement to dilute a concentrated drugs introduces increased risk of delay and contamination or error, all of which can be dangerous to patient health.

39. To address this problem, Nexus developed an alternative, and submitted New Drug Application NDA No. 213407 to the FDA for approval of its stable, ready-to-use ephedrine sulfate product at a concentration of 5 mg/mL. Nexus invested significant resources over several years to prepare NDA No. 213407.

40. The FDA approved Nexus's NDA No. 213,407 on April 17, 2020 under the trade name EMERPHED®. Nexus's EMERPHED® product is the first FDA-approved stable, ready-to-use ephedrine sulfate product on the market in the United States.

41. Nevakar developed an ephedrine sulfate product, but that product was developed later in time and infringes Nexus's '278 patent. Also later in time, Nevakar applied for its own patent on an ephedrine sulfate product. That patent is invalid and Nexus does not infringe it. Nonetheless, Defendants have threated to assert Nevakar's '845 patent against Nexus in view of Nexus's commercial sales of EMERPHED®.

THE PATENT-IN-SUIT

42. Nexus pursued patent protection for its novel ephedrine sulfate product that

provides benefits to doctors, nursing staff, and ultimately patients.

43. The ’278 patent, entitled “Compositions Comprising Ephedrine Or An Ephedrine Salt And Methods Of Making And Using The Same,” was duly and legally issued on August 17, 2021, naming Shahid Ahmed as the inventor. A true and correct copy of the ’278 patent is attached hereto as Exhibit A.

44. The independent claims of the ’278 patent generally relate to methods for administering ephedrine sulfate to a subject having hypotension or an elevated risk of developing hypotension in need thereof, and delivering a shelf-stable ready-to-use ephedrine sulfate pharmaceutical product comprising 5 mg/mL ± 5% ephedrine sulfate, 9 mg/mL sodium chloride, no preservative, and water into a subject. The dependent claims of the patent provide limitations that relate to the glass vial containing the solution, the sterilization of the product, the stability of the product under specific conditions, the process for preparing the solution, and the pH of the solution.

45. Nexus is the assignee and lawfully owns all right, title, and interest in the ’278 patent, including the right to sue and to recover for infringement thereof.

46. For the past several weeks, Nevakar and Endo have discussed the Nevakar patent with Nexus. When the Patent Office approved the Nexus patent claims that have now issued as part of the ’278 patent, Nevakar and Endo reported to Nexus that they were aware of Nexus’s pending patent application and the approved claims that have now issued as part of the ’278 patent. On information and belief, Nevakar and Endo are aware of Nexus’s issued ’278 patent, and have been tracking the pending application through issuance.

DEFENDANT’S NDA NO. 213994

47. On information and belief, Nevakar submitted NDA No. 213994 to the FDA

under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act, seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a 5 mg/mL ephedrine sulfate injection product (hereinafter "Defendants' NDA Product").

48. Nevekar initially filed NDA No. 213994 seeking FDA approval of Defendants' NDA product. On information and belief, while Nevakar will manufacture for commercial sale Defendants' NDA Product, Nevakar has transferred ownership of NDA No. 213994 to Endo. On information and belief, EIP will direct Par to sell and distribute, and Par will sell and distribute on behalf and at the behest of, Endo and EIP the product of NDA No. 213994 that will be manufactured by Nevakar.

49. On or about October 16, 2020, FDA approved NDA No. 213994. Publicly available information, including FDA's review of Defendants' NDA Product, the approved product label for Defendants' NDA Product, and Nevakar's patent, describe Defendants' NDA Product, how it is manufactured, and how to administer it to patients. Defendants will teach or encourage doctors or healthcare provided to administer the ephedrine sulfate described in the claims, made by the processes described in the claims, for the methods described in the claims with the specific intent that such individuals will practice the claimed methods. Defendants will also contribute to infringement by selling a product that does not have substantial non-infringing uses.

50. Specifically, on information and belief, Defendants' NDA Product is a sterile, shelf-stable, ready-to-use solution presented in a sealed glass vial that comprises 5 mg/mL ephedrine sulfate, 9 mg/mL sodium chloride, and water with a pH of between 4 and 7. Reported information including on the Defendants' product label shows a ready-to-use vial that is shelf-stable and comprises 5 mg/mL ephedrine sulfate. On information and belief, Defendants' NDA

Product does not contain a preservative. Reported information including on the Defendants' product label does not show there is any preservative contained in the formulation. On information and belief, Defendants filter their product using a membrane. On information and belief Defendants terminally sterilize their finished dosage form. On information and belief, Defendants' NDA Product is shelf-stable for 24 months, and is stable at both ambient and accelerated conditions. On information and belief, Defendants' NDA Product labeling instructs health care providers to administer Defendants' NDA Product to a subject having hypotension or at an elevated risk of developing hypotension by drawing the solution from the sealed glass vial with a syringe and administering to that subject. Reported information including on the Defendants' product label provides this indication.

51. Because Defendants' NDA Product has been approved by FDA, Defendants can manufacture, offer for sale, and sell its ready-to-use ephedrine sulfate injection solution product. On information and belief, the manufacture of Defendants' NDA Product is imminent, and the sale of actual products will be occurring very soon.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 11,090,278

52. Nexus incorporates and realleges paragraphs 1-51 above.

53. Nevekar committed an act of infringement under 35 U.S.C. § 271(e)(2) by submitting NDA No. 213994 to the FDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States for a drug claimed in the '278 patent or for the use of which is claimed in the '278 patent. On information and belief, Nevakar will manufacture for commercial sale Defendants' NDA Product and sell it to Par and Endo, with the labeled

instructions for use. These acts constitute infringement under 35 U.S.C. §§ 271(a), (b), and (c).

54. On information and belief, Nevakar has transferred ownership of NDA No. 213994 to Endo and Endo has made additional submissions to the FDA regarding its 505(b)(2) product. Endo thus committed an act of infringement under 35 U.S.C. § 271(e)(2). On information and belief, Endo, EIP, and Par operate as one entity for purposes of selling commercial pharmaceutical products, including the ephedrine sulfate product at issue in this case. On information and belief, Endo will work in concert with EIP and Par to offer for sale and sell Defendants' NDA Product, with the labeled instructions for use. These acts constitute infringement under 35 U.S.C. §§ 271(a), (b), and (c).

55. On information and belief, Par will offer for sale and sell Defendants' NDA Product. On information and belief, Endo, EIP, and Par operate as one entity for purposes of selling commercial pharmaceutical products, including the ephedrine sulfate product at issue in this case. On information and belief, Endo will work in concert with EIP and Par to offer for sale and sell Defendants' NDA Product, with the labeled instructions for use. These acts constitute infringement under 35 U.S.C. §§ 271(a), (b), and (c).

56. On information and belief, EIP will direct Par and Endo to offer for sale and sell Defendants' NDA Product. On information and belief, Endo, EIP, and Par operate as one entity for purposes of selling commercial pharmaceutical products, including the ephedrine sulfate product at issue in this case. On information and belief, Endo will work in concert with EIP and Par to offer for sale and sell Defendants' NDA Product, with the labeled instructions for use. These acts constitute infringement under 35 U.S.C. §§ 271(a), (b), and (c).

57. Individually and collectively, Defendants' past and imminent manufacture, importation, use, offer for sale, and sale of Defendants' NDA Product constitutes infringement of

the ’278 patent under 35 U.S.C. § 271(a), (b), and/or (c), and 28 U.S.C. § 2201.

58. On information and belief, Defendants’ NDA Product is covered by each claim of the ’278 patent, and its actions will induce infringement of the ’278 patent. On information and belief, Defendants’ NDA Product is covered by each claim of the ’278 patent, and its actions will contribute to the infringement of the ’278 patent.

59. On information and belief, Defendants’ commercial importation, manufacture, use, sale, and/or offer for sale of Defendants’ NDA Product before the expiration of the ’278 patent will directly or indirectly infringe the claims of the ’278 patent.

60. The ’278 patent has 14 claims directed to a methods for administering a shelf-stable, ready-to-use ephedrine sulfate product to a subject having hypotension or an elevated risk of hypotension. Defendants’ NDA Product meets each and every limitation of claims 1-14 of the ’376 patent, either literally or under the doctrine of equivalents.

61. Independent claim 1 of the ’278 patent is directed to:

> A method of administering ephedrine sulfate to a subject having hypotension or an elevated risk of developing hypotension in need thereof, the method consisting essentially of:
>
> drawing a shelf-stable ready-to-use ephedrine sulfate composition from a sterile premixed pharmaceutical product into a syringe; and
> injecting the composition into the subject using the syringe,
>
> wherein the shelf-stable ready-to-use ephedrine sulfate composition consists essentially of:
> 5 mg/mL +/- 5% ephedrine sulfate;
> 9 mg/mL sodium chloride;
> no preservative; and
> water, and
>
> wherein the shelf-stable ready-to-use ephedrine sulfate composition is prepared by a process comprising:
> combining ephedrine sulfate, sodium chloride, and water to form a solution comprising 5 mg/mL +/- 5% of ephedrine sulfate and 9 mg/mL sodium chloride;

placing the solution into depyrogenated glass vials;
sealing the filled glass vials; and
terminally sterilizing the sealed glass vials.

62. Independent claim 8 of the ’278 patent is directed to:

A method of administering ephedrine sulfate to a subject having hypotension or an elevated risk of developing hypotension in need thereof, the method comprising:
drawing a shelf-stable ready-to-use ephedrine sulfate pharmaceutical product comprising 5 mg/mL +/- 5% ephedrine sulfate and no preservative from a sealed glass vial into a syringe; and
injecting the composition into the subject using the syringe,

wherein the shelf-stable ready-to-use ephedrine sulfate pharmaceutical product is prepared by a process comprising:
combining ephedrine sulfate, sodium chloride, and water to form a solution consisting essentially of 5 mg/mL +/- 5% of ephedrine sulfate and 9 mg/mL sodium chloride and having an initial pH level;
thereafter filtering the solution through a membrane filter to form a filtered solution;
thereafter placing the filtered solution into depyrogenated glass vials;
sealing the filled glass vials; and
terminally sterilizing the sealed glass vials by an overkill terminal sterilization process.

63. Consistent with these claims, and based on publicly available information and on information and belief, Defendants’ NDA Product is a sterile, shelf-stable, ready-to-use 5 mg/mL ephedrine sulfate product meeting each and every limitation of claims 1 and 8 of the ’278 patent literally or equivalently. Moreover, the package label for Defendants’ NDA Product instructs doctors and healthcare providers to practice the methods of claims 1 and 8 in treating patients having hypotension or at an elevated risk of developing hypotension.

64. Upon information and belief, Defendants’ NDA Product meets the additional elements contained in claims 2-7 and 9-14 of the ’278 patent, either literally or under the doctrine of equivalents, and Defendants directly or indirectly infringe those claims.

65. On information and belief, unless enjoined by this Court, Defendants’ manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’

NDA Product with its proposed labeling Defendants will infringe, either literally or under the doctrine of equivalents, one or more of claims of the ’278 patent.

66. On information and belief, Defendants have been monitoring the patent application that resulted today in the ’278 patent, reported their knowledge to Nexus about the pending claims and the approval of the claims that are now issued as part of the ’278 patent, and are aware of the existence of the ’278 patent.

67. On information and belief, Defendants have no reasonable basis for believing that Defendants’ NDA Product will not infringe one or more valid claims of the ’278 patent and no reasonable basis for believing that the infringed claims are invalid. Defendants do not have commercial sales of the Defendants’ NDA Product to date, but if they do elect to sell the infringing product despite the allegations in this Complaint and knowledge of the ’278 patent, then any such infringement will be willful.

68. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

69. 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.

70. Nexus is entitled to the relief provided by 35 U.S.C. § 271(e)(4). In addition, Nexus is entitled to an injunction prohibiting Defendants from manufacturing, using, offering for sale, or selling Defendants’ NDA Product in the United States before expiration of the ’278 patent.

COUNT II

DECLARATION OF NON-INFRINGEMENT OF U.S. PATENT NO. 10,869,845

71. Nexus incorporates and realleges paragraphs 1-70 above.

72. Nevakar and Endo have threatened suit against Nexus for infringement of the

'845 patent by Nexus's manufacture, offer for sale, and sale of Nexus's EMERPHED® product. Based on that allegation, there is now a ripe dispute a between the parties regarding whether the claims of the '845 patent are valid or infringed.

73. Nexus's EMERPHED® product will not infringe any properly construed valid claim of the '845 patent because EMERPHED® does not meet one or more limitations of the claims of the '845 patent and because Nexus cannot infringe an invalid or unenforceable patent. The claims of the '845 patent are invalid based on prior art including Nexus's own '278 patent.

74. Therefore, Nexus is entitled to a declaration of non-infringement and invalidity of the '845 patent.

PRAYER FOR RELIEF

WHEREFORE, Nexus respectfully requests the following relief:

A. Judgment in favor of Nexus and against Nevakar, Par, Endo, and EIP individually and collectively;

B. Judgment, pursuant to 35 U.S.C. § 271(e)(2), 35 U.S.C. § 271(a), (b), and/or (c), and 28 U.S.C. § 2201, that Nevakar, Par, Endo, and EIP individually and collectively, has infringed, literally or by the doctrine of equivalents, the '278 patent by the submission of NDA No. 213944, and that the importation, sale, offer for sale, use, and/or manufacture of Defendants' NDA Product, in the United States, would infringe the '278 patent;

C. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(B) and other provisions of 35 U.S.C. § 271, that Defendants are prevented from manufacturing, using, selling, or offering to sell Defendants' NDA Product until a date not earlier than the date of expiration of the '278

patent plus any additional periods of exclusivity;

D. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271 and 283 and Federal Rule of Civil Procedure 65, enjoining Nevakar, Par, Endo, and EIP, and those entities' officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any Defendants' NDA Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the '278 patent and any additional periods of exclusivity;

E. A declaration that this is an exceptional case and an award to Nexus of its reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

F. Damages or other monetary relief, including prejudgment interest, if Defendants engage in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of Defendants' NDA Product, or any other products that would infringe or induce infringement of the '278 patent prior to the expiration of the '278 patent;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. A declaration that Nexus does not infringe the '845 patent and that the '845 patent is invalid;

I. An award of Nexus's taxable costs in bringing and prosecuting this action; and

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

proper.

Respectfully submitted,
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