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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS, LLP, Plaintiffs, v. NEVAKAR INJECTABLES, INC., and ENDO VENTURES LTD., Defendant.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Ingenus Pharmaceuticals, LLC, and Leiutis Pharmaceuticals, LLP (collectively, "Plaintiffs"), for their Complaint against Defendants Nevakar Injectables, Inc. ("Nevakar") and Endo Ventures Ltd. ("Endo") (collectively "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., involving U.S. Patent No. 10,993,952 ("the '952 patent" or "the patent in suit"), attached hereto as Exhibit A.

THE PARTIES

2. Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839. Leiutis Pharmaceuticals, LLP ("Leiutis") is a corporation organized and existing under the laws of the country of India, having its principal place of business at Plot No 23, 4th and 5th Floor, VSR Complex Technocrafts Industrial Estate, 1st Phase, Balanagar, Hyderabad, Telangana 500037, India.

3. Upon information and belief, Nevakar Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 1019 US Highway 202-206, Building K, NJ Center of Excellence, Bridgewater, NJ 08807.

4. Upon information and belief, Nevakar Inc. is a fully integrated, privately held, late-stage biopharmaceutical company with an extensive portfolio of products in the sterile-injection and ophthalmic areas, and is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical and injectable products throughout the United States, including in New Jersey.

5. On information and belief, Nevakar Injectables Inc. (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 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.

6. Upon information and belief, Nevakar derives substantial revenue from the sale of generic pharmaceutical products in the United States and New Jersey.

7. Upon information and belief, Endo is a corporation organized and existing under the laws of Ireland, having its principal place of business at First Floor - Minerva House, Simmonscourt Road, Dublin 4 Dublin, D04 H9P8 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 Endo International plc.

8. Upon information and belief, Endo is in the business of, among other things, developing, manufacturing, marketing, sale, using, distribution, and importing into the United States, generic versions of branded pharmaceutical products for the U.S. markets.

9. Upon information and belief, Endo derives substantial revenue from the importation and sale of generic pharmaceutical products in the United States and New Jersey.

10. Upon information and belief, Nevakar and Endo collaborated in the preparation and submission of New Drug Application (NDA) No. 217651.

11. Upon information and belief, Nevakar and Endo continue to collaborate in pursuing FDA approval of that NDA to engage in commercial use, sale, and/or distribution of cyclophosphamide solution 500 mg/2.5 ml (200 mg/ml), 1 gm/5 ml (200 mg/ml), and 2 gm/10 ml (200 mg/ml), throughout the U.S., including New Jersey, before the expiration of the '952 patent.

JURISDICTION AND VENUE

12. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271 *et seq*., and alleges infringement of the '952 Patent.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, because this action involves claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq*.).

14. This Court has personal jurisdiction over Nevakar at least because, upon information and belief, Nevakar is incorporated in New Jersey, has a principal place of business at 1019 US Highway 202 #206, Bridgewater, New Jersey 08807, regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey; thereby demonstrating that Nevakar has continuous and systematic contacts with New Jersey.

15. On information and belief, Nevakar 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.

16. On information and belief, Nevakar purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of Nevakar's pharmaceutical products.

17. This Court has personal jurisdiction over Nevakar at least because, upon information and belief, if Nevakar and Endo's NDA Products receive final approval, Nevakar and Endo's NDA Products will be manufactured, sold, distributed, and/or used by Nevakar in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

18. 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.

19. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Cyclophosphamide Injection for sale and use throughout the United States, including this judicial district.

20. On information and belief, Nevakar and Endo 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. 11, 2021) and *Nexus Pharmaceuticals, Inc. v. Nevakar, Inc. et al.,* Case No. 1:22-cv-05683-RMB–SAK (filed Sept. 23, 2022).

21. On information and belief and as indicated by a letter dated November 17, 2022 sent by Defendants to Ingenus Pharmaceuticals LLC and Leiutis Pharmaceuticals LLP pursuant to 21 U.S.C. § 355(j)(2)(B)(i) (hereinafter, the "Notice Letter"), NDA No. 217651 was prepared and filed with the intention of seeking to market the NDA Products nationwide, including within this judicial district.

22. On information and belief, Defendants plan to sell the NDA Products in the State of New Jersey and seek Medicaid reimbursements for sales of the NDA Products in the State of

New Jersey, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

23. On information and belief, Defendants intend that the NDA Products will be distributed and sold in New Jersey and will thereby displace sales of Plaintiffs' Cyclophosphamide Injection, causing injury to Ingenus and Leiutis. Defendants intend to take advantage of its established channels of distribution in New Jersey for the sale of the NDA Products.

24. Additionally, this Court has personal jurisdiction over Endo because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Endo is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Endo has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of NDA No. 217651, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Endo satisfies due process.

25. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

26. Venue is proper in this district for Endo pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Endo is a corporation organized and existing under the laws of Ireland and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

27. Venue is proper in this district for Nevakar pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Nevakar is subject to personal jurisdiction and has a principal place of business in this judicial district.

PLAINTIFFS' APPROVED DRUG PRODUCT AND U.S. PATENT

28. Ingenus is the holder of New Drug Application (NDA) No. 212501, which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide injection for intravenous use ("NDA Products"). The active ingredient in Plaintiffs' Cyclophosphamide injection Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

29. Ingenus' NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL) in a multiple-dose vial. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under Application No. N212501.

30. Cyclophosphamide is an injectable solution indicated for the treatment of malignant diseases such as malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma), multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia, acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia), mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma.

31. Cyclophosphamide's recommended dosage is 40 mg per kg to 50 mg per kg in divided doses over 2 to 5 days.

32. The '952 Patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021. A true and correct copy of the '952 Patent is attached hereto as Exhibit A.

33. Leiutis and Ingenus are the owners and assignees of the '952 Patent

34. Pursuant to 21 U.S.C. § 355(b)(1), the '952 patent was submitted to the FDA with NDA No. 212501 and was subsequently listed in the Approved Drug Products with Therapeutic

Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

DEFENDANTS' NDA NO. 217651

35. On information and belief, Defendants have submitted NDA No. 217651 to FDA, or caused NDA No. 217651 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiffs' NDA Products prior to the expiration of the '952 Patent.

36. On information and belief, FDA has not approved Defendants' NDA.

37. On information and belief, Defendants sent Ingenus and Leiutis a Notice Letter dated November 17, 2022. The Notice Letter represents that Defendants had submitted to FDA NDA No. 317651 and a purported Paragraph IV certification for the '952 Patent. Plaintiffs reserve all rights to challenge the sufficiency of Defendants' NDA and Notice Letter.

38. On information and belief, the purpose of an NDA and Paragraph IV certification is to obtain approval under section 505(j) of the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture and sale of the NDA Products before expiration of the '952 Patent. Hence, Defendants' purpose in submitting NDA No. 217651 is to market the products described therein before the expiration of the '952 Patent.

39. On information and belief, if approved, the NDA Products will have the same indication as Plaintiffs' Cyclophosphamide Injection Product. On further information and belief, the indication set forth in the proposed labeling submitted in NDA No. 217651 for the NDA Products is the treatment of malignant diseases as described in Plaintiffs' NDA.

40. On information and belief, if FDA approves Defendants' NDA, Defendants will manufacture, offer for sale, or sell the NDA Products, within the United States, including within

the State of New Jersey, or will import the NDA Products into the United States, including the State of New Jersey.

41. On information and belief, if FDA approves Defendants' NDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the NDA Products in a manner that infringes the '952 Patent.

42. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

FIRST COUNT
(Defendants' Infringement of the '952 Patent)

43. Plaintiff's repeat and re-allege each of the foregoing paragraphs 1-42 as fully set forth therein.

44. Upon information and belief, Defendants submitted or caused the submission of NDA No. 217651 to FDA, and thereby requests FDA approval of Defendants' NDA.

45. Plaintiffs own all rights, title, and interest in and to the '952 Patent.

46. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of NDA with a Paragraph IV certification to the '952 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Nevakar and Endo's NDA Products before the expiration of the '952 patent is itself an act of infringement of the '952 patent.

47. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of Nevakar and Endo's NDA Products within the United States will infringe, either literally or under the doctrine of equivalents, one or more claims of the '952 Patent under 35 U.S.C. § 271(a).

48. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '952 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA

approval of Defendants' NDA, Defendants will make, use, offer to sell, or sell Nevakar and Endo's NDA Products within the United States, or will import Nevakar and Endo's NDA Products into the United States, and will thereby induce infringement of one or more claims of the '952 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '952 Patent and knowledge that their acts are encouraging infringement.

49. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '952 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' NDA, Defendants will offer to sell or sell Nevakar and Endo's NDA Products within the United States, or will import Nevakar and Endo's NDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '952 Patent. On information and belief, Defendants have and continues to have knowledge of the '952 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants had and continue to have knowledge that Nevakar and Endo's NDA Products are especially made or especially adapted for a use that infringes the '952 Patent and that there are no substantial noninfringing uses for Nevakar and Endo's NDA Products

50. Defendants had actual and constructive notice of the '952 Patent prior to filing Defendants' NDA, and were aware that the filing of Defendants' NDA with the request for FDA approval prior to the expiration of the '952 Patent would constitute an act of infringement of the '952 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Nevakar and Endo's NDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '952 Patent.

51. Defendants filed their NDA without adequate justification for asserting the '952 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Nevakar and Endo's NDA Products. Defendant's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '952 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

52. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '952 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the following relief:

A. A judgment that Defendants have infringed the '952 Patent under 35 U.S.C. § 271(e)(2)(A);

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' NDA shall be no earlier than the last expiration date of the '952 Patent, or any later expiration of exclusivity for the '952 Patent, including any extensions or regulatory exclusivities;

C. Entry of a permanent injunction enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf from commercially manufacturing, using, offering for sale, or selling Nevakar and Endo's NDA Products within the United States, or importing

Nevakar and Endo's NDA Products into the United States, until the expiration of the '952 Patent;

D. A judgment that making, using, selling, offering to sell, or importing Nevakar and Endo's NDA Products, or inducing or contributing to such conduct, would constitute infringement of the '952 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration that if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Nevakar and Endo's NDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Nevakar and Endo's NDA Products, or any product that infringes the '952 Patent, or induces or contributes to such conduct, prior to the expiration of the '952 Patent;

G. An order staying approval of Nevakar and Endo's NDA for a 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii);

H. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other and further relief as the Court deems just and proper.

Dated: December 30, 2022

Respectfully Submitted,

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: December 30, 2022

Respectfully Submitted:

By: *s/ Gregory D. Miller*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiff seeks, *inter alia*, declaratory relief.

Dated: December 30, 2022

s/ Gregory D. Miller
Gregory D. Miller