UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS LLP,	)	
Plaintiffs,	)	
v.	)	C.A. No.
NEXUS PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Ingenus Pharmaceuticals, LLC, and Leiutis Pharmaceuticals LLP (collectively, "Plaintiffs"), by their undersigned attorneys, for their complaint against Defendant Nexus Pharmaceuticals, Inc. ("Nexus" or "Defendant") herein, 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, Title 35 of the United States Code, involving U.S. Patent No. 10,993,952 ("the '952 patent" or "the patent in suit"). A true and correct copy of the '952 patent is 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, 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.

4. Upon information and belief, Nexus is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Illinois.

5. Upon information and belief, Nexus derives substantial revenue from the sale of generic pharmaceutical products in the United States and Illinois.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the ’952 patent.

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

8. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is incorporated in Illinois; has its principal place of business in Lincolnshire, Illinois; regularly does or solicits business in Illinois; engages in other persistent courses of conduct in Illinois; and/or derives substantial revenue from services or things used or consumed in Illinois; thereby demonstrating that Nexus has continuous and systematic contacts with Illinois, and within this judicial district.

9. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is the current owner of Abbreviated New Drug Application (ANDA) No. 216783 ("Nexus's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL and 1 mg/5 mL (200 mg/mL) ("Nexus's ANDA Product" or "ANDA Product"), throughout the United States, including in Illinois and within this judicial district, before the expiration of the '952 patent.

10. This Court has personal jurisdiction over Nexus at least because, upon information and belief, if Nexus's ANDA receives final approval, Nexus's ANDA Product will be manufactured, sold, distributed, and/or used by Nexus in Illinois and within this judicial district; prescribed by physicians practicing in Illinois and within this judicial district; and/or administered to patients in Illinois and within this judicial district.

11. Defendant has 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 within this judicial district. On information and belief and as indicated by a letter dated April 21, 2022, sent by Nexus Pharmaceuticals, Inc. to Ingenus Pharmaceuticals LLC and Leiutis Pharmaceuticals LLP pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (hereinafter, the "Notice Letter"), ANDA No. 212501 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

12. On information and belief, Defendant plans to sell its ANDA Product in the State of Illinois and within this judicial district, list the ANDA Product on the State of

Illinois' prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Illinois, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

13. On information and belief, Defendant intends that its proposed ANDA Product will be distributed and sold in Illinois and within this judicial district and will thereby displace sales of Plaintiffs' Cyclophosphamide Injection, causing injury to Ingenus and Leiutis. Defendant intends to take advantage of its established channels of distribution in Illinois for the sale of its proposed ANDA Product.

14. Nexus Pharmaceuticals, Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g,. Melinta Therapeutics, LLC et al v. Nexus Pharmaceuticals, Inc*., 1:21-cv-02636; *Medicure International, Inc. v. Nexus Pharmaceuticals, Inc*., 1:19-cv-07979.

15. In its Paragraph IV certification accompanying Nexus's ANDA, Nexus stated "Venue is appropriate in the Northern District of Illinois."

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

PLAINTIFFS' APPROVED DRUG PRODUCT AND U.S. PATENT

17. 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 solution for intravenous use ("NDA Product"). The

active ingredient in Plaintiffs' Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

18. 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 New Drug Application No. N212501.

19. Plaintiffs' Cyclophosphamide NDA Product is an injectable solution indicated for the treatment of malignant diseases such 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.

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

21. 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.

22. Leiutis and Ingenus are the owners and assignees of the '952 patent.

23. Pursuant to 21 U.S.C. § 355(b)(1), the '952 patent was submitted to FDA with NDA No. 212501and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

DEFENDANT'S ANDA NO. 216783

24. On information and belief, Defendant has submitted ANDA No. 216783 to FDA, or caused ANDA No. 216783 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 Product prior to the expiration of the '952 patent.

25. On information and belief, FDA has not approved Defendant's ANDA.

26. On information and belief, Nexus sent Ingenus and Leiutis a Notice Letter dated April 21, 2022. The Notice Letter represents that Nexus had submitted to FDA ANDA No. 216783 and a purported Paragraph IV certification for the '952 patent. Plaintiffs reserve all rights to challenge the sufficiency of Defendant's ANDA and Notice Letter.

27. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Product before expiration of the '952 patent. Hence, Defendant's purpose in submitting ANDA No. 216783 is to market the ANDA product described therein before the expiration of the '952 patent.

28. On information and belief, if approved, the ANDA Product will have the same indication as Plaintiffs' Cyclophosphamide NDA Product. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 216783 for the ANDA Product is the treatment of malignant diseases as described in Plaintiffs' NDA.

29. On information and belief, if FDA approves Defendant's ANDA, Defendant will manufacture, offer for sale, or sell the ANDA Product, within the United States, including within the State of Illinois and this judicial district, or will import the ANDA Product into the United States, including into the State of Illinois and this judicial district.

30. On information and belief, if FDA approves Defendant's ANDA, Defendant will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '952 patent.

31. 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
(Nexus's Infringement of the '952 Patent)

32. Plaintiffs repeat and re-allege each of the foregoing paragraphs 1-31 as fully set forth therein.

33. Upon information and belief, Nexus submitted or caused the submission of ANDA No. 216783 to FDA, seeking FDA approval of Defendant's ANDA.

34. Plaintiffs own all rights, title, and interest in and to the '952 patent.

35. The ANDA Product falls within one or more claims of the '952 patent.

36. Nexus does not contest infringement of any claims of the '952 patent in its Notice Letter. If Nexus had a factual or legal basis to contest infringement of any claims of the '952 patent, Nexus was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

37. Under 35 U.S.C. § 271(e)(2)(A), Nexus's submission of Nexus's ANDA 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 Nexus's ANDA Product before the expiration of the '952 patent is itself an act of infringement of the '952 patent.

38. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product 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).

39. Unless enjoined by this Court, upon FDA approval, Defendant will actively induce infringement of the '952 patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product 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, Defendant will intentionally encourage acts of direct infringement with knowledge of the '952 patent and knowledge that its acts are encouraging infringement.

40. Unless enjoined by this Court, upon FDA approval, Defendant will contributorily infringe the '952 patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will offer to sell or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '952 patent. On information and belief, Defendant has had and continues to have knowledge of the '952 patent and knowledge that its acts will lead to infringement of the

patent. On information and belief, Defendant has had and continues to have knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the ’952 patent and that there are no substantial noninfringing uses for the ANDA Product.

41. Defendant had actual and constructive notice of the ’952 patent prior to filing Defendant’s ANDA, and was aware that the filing of Defendant’s ANDA with the request for FDA approval prior to the expiration of the ’952 Patent would constitute an act of infringement of the ’952 patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, and/or induce the infringement of the ’952 patent.

42. Defendant filed its ANDA 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 the ANDA Product. Defendant’s conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the ’952 patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

43. Plaintiffs will be irreparably harmed if Defendant is 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 Defendant, 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 request the following relief:

A. A judgment that Defendant has 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' ANDA 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 Defendant, its 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 the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the '952 patent;

D. A judgment that making, using, selling, offering to sell, or importing the ANDA Product, 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 under 28 U.S.C. § 2201 that if Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Product, 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 Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or

importation of the ANDA Product, 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 Nexus's ANDA 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 and costs to Plaintiffs in this action pursuant to 35 U.S.C. § 285; and

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

Dated: June 1, 2022

Respectfully submitted,

By: */s/ Christopher T. Griffith*

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