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

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS LLP,	)	
Plaintiffs,	)	
v.	)	
NEXUS PHARMACEUTICALS, INC.,	)	C.A. 1-22-cv-02868 (MMR)
Defendant.	)	

NEXUS'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM TO COMPLAINT

Defendant Nexus Pharmaceuticals, Inc. ("Nexus" or "Defendant"), by and through its counsel, answers the Complaint of Plaintiffs Ingenius Pharmaceuticals, LLC., and Leiutis Pharmaceuticals, LLP (collectively "Plaintiffs") as follows. All allegations not specifically admitted are denied.

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.

ANSWER: Nexus admits that Plaintiff's Complaint purports that this is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 10,993,952, which appears to be attached as Exhibit A, but denies that Plaintiff is entitled to any relief.

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.

ANSWER: Upon information and belief, admitted.

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.

ANSWER: Admitted.

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.

ANSWER: Nexus admits that it is in the business of, among other things, the development, manufacture, and sale of pharmaceutical products. Otherwise, denied.

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

ANSWER: Denied.

JURISICTION 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.

ANSWER: Nexus admits that Plaintiff's Complaint purports that this is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 10,993,952, which appears to be attached as Exhibit A, but denies that Plaintiff is entitled to any relief.

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

ANSWER: Paragraph 7 contains conclusions of law for which no response is required. To the extent that a response is required, Nexus does not object to subject matter jurisdiction for this particular action.

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.

ANSWER: Nexus admits that it is incorporated in Illinois and has a place of business in Illinois, but otherwise denies all remaining allegations of paragraph 8.Nexus does not object to personal jurisdiction for this particular action.

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.

ANSWER: Nexus admits that it is the owner of ANDA No. 216783 for of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL and 1 mg/5 mL (200 mg/mL) and is seeking approval of that ANDA. Nexus denies all remaining allegations of paragraph 9 .Nexus does not object to personal jurisdiction for this particular action.

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.

ANSWER: Paragraph 10 contains conclusions of law for which no response is required. To the extent that a response is required, Nexus does not object to personal jurisdiction for this particular action. Nexus states that the allegations refer to future actions which have not occurred and therefore Nexus lacks knowledge or information sufficient to form a belief about the truth of the allegations.

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.

ANSWER: Denied.

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.

ANSWER: Nexus states that the allegations refer to future actions which have not occurred and therefore Nexus lacks knowledge or information sufficient to form a belief about the truth of the allegations.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 16 contains conclusions of law for which no response is required. To the extent that a response is required, Nexus does not object to venue for this particular action.

BACKGROUND

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.

ANSWER: Upon information and belief, Nexus admits that the FDA website lists Ingenus as the holder of NDA No. 212501 for Cyclophosphamide solution for intravenous use. Nexus lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 17.

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.

ANSWER: Upon information and belief, Nexus admits that NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/2.5 mL, 1 g/ 5 mL, and 2 g/ 10ml) in a multiple-dose vial. Nexus lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 18.

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.

ANSWER: Nexus admits that Plaintiffs' Cyclophosphamide NDA Product is indicated for the treatment of "Malignant Diseases: malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias; mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, and breast carcinoma. Nexus denies the remaining allegations of paragraph 19.

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.

ANSWER: Denied.

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.

ANSWER: On information and belief, Nexus admits that, on its face, the ’952 patent is titled “Stable Ready to Use Cyclophosphamide Liquid Formulations” and states that it was issued on May 4, 2021. Nexus denies that the patent was duly and legally issued.

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

ANSWER: Nexus admits that Leiutis is listed as the assignee on the face of the ‘952 patent. Nexus denies the remaining allegations of paragraph 22.

23. Pursuant to 21 U.S.C. § 355(b)(1), the ’952 patent was submitted to 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.

ANSWER: Nexus admits that the Orange Book currently lists the ’952 patent in connection with NDA No. 212501 for Cyclophosphamide Injection. Nexus lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 23.

DEFENDANT’S ANDA NO. 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.

ANSWER: Nexus admits that it submitted ANDA No. 216783 to the FDA, pursuant to the FDCA, and that Nexus's ANDA refers to NDA No. 212501 for cyclophosphamide injection. Nexus denies all remaining allegations of paragraph 24.

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

ANSWER: Nexus admits that its ANDA has not yet been approved.

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.

ANSWER: Nexus admits it sent Ingenus and Leiutis a Notice Letter dated April 21, 2022 that references ANDA No. 216783 and a Paragraph IV certification for the '952 patent. Nexus denies all remaining allegations of paragraph 26.

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.

ANSWER: Denied.

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.

ANSWER: Nexus lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 28 and therefore denies them, as the paragraph addresses future activity about which a decision has not been made.

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.

ANSWER: The statement refers to future activity for which no determination has been made, so Nexus denies the allegation of paragraph 29.

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.

ANSWER: Denied.

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).

ANSWER: Paragraph 31 includes conclusions of law for which no response is required.

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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.

ANSWER: Nexus incorporates its answers to each of the foregoing paragraphs as if fully set forth herein.

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

ANSWER: Admitted.

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

ANSWER: Nexus admits that Leiutis is listed as the assignee on the face of the '952 patent. Nexus denies the remaining allegations of paragraph 34.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Nexus denies all allegations of infringement and that Plaintiffs are entitled to any relief. Nexus respectfully requests that the Court dismiss Plaintiffs' Complaint with prejudice, enter

judgment in favor of Nexus, award Nexus its reasonable attorneys' fees and costs incurred in defending this suit, and award Nexus such other relief as the Court deems just and proper.

NEXUS'S AFFIRMATIVE DEFENSES

First Affirmative Defense

The claims of the '952 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Second Affirmative Defense

Plaintiffs are not entitled to relief because they have not appropriately shown nor proven adequate standing for the relief sought.

Third Affirmative Defense

Plaintiffs are barred by 35 U.S.C. § 233 from recovering any costs associated with this suit.

Fourth Affirmative Defense

The Complaint, in whole or in part, fails to state a claim upon which relief may be granted, and fails to identify any claims that might infringe or a plausible basis for why they are infringed.

Fifth Affirmative Defense

Plaintiffs' cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel and other doctrines that limit the application of the claims to the accused products.

Plaintiffs are estopped from arguing and have waived arguments that its claims cover Nexus's ANDA product based on the amendments, positions, and arguments made to the USPTO when obtaining the asserted patent.

Reservation of Additional Defenses

Nexus reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of one or more of the patents-in-suit.

WHEREFORE, Nexus prays that the Court enter judgment in its favor and against Plaintiffs as follows:

a) Adjudging that no patent claim asserted by Plaintiffs is valid or infringed;

b) Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Nexus or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Nexus, or charging them either orally or in writing with infringement of any patent asserted herein against Nexus;

c) Granting Nexus judgment in its favor on Plaintiffs' Complaint;

d) Denying Plaintiffs' request for injunctive relief;

e) Dismissing Plaintiffs' Complaint with prejudice;

f) Declaring that the claims of the '952 patent are invalid;

g) Requiring that all costs be taxed against Plaintiffs;

h) Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Nexus its costs and reasonable attorneys' fees; and

i) Awarding any other such relief as is just and proper.

NEXUS'S COUNTERCLAIM

Defendant/Counterclaim-Plaintiff Nexus Pharmaceuticals, Inc. ("Nexus"), by and through its counsel, brings the following Counterclaim against Plaintiffs/Counterclaim-Defendants Ingenus Pharmaceuticals, LLC, and Leiutis Pharmaceuticals, LLP. ("Counterclaim-Defendants" or "Plaintiffs") for a declaratory judgment that U.S. Patent No. 10,993,952 ("the '952 patent") is invalid and/or not infringed by the cyclophosphamide solution for intravenous injection that is the subject of Abbreviated New Drug Application ("ANDA") No. 216783 ("Nexus's Proposed ANDA Product").

THE PARTIES

1. 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.

2. Upon information and belief, 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. Upon information and belief, 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.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over the counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), based on an actual, substantial, continuing and justiciable controversy between Nexus and Counterclaim-Defendant arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

4. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have voluntarily subjected itself to the Court's jurisdiction by filing the Complaint, and have purposefully availed themselves of the benefits of jurisdiction in this State.

5. Counterclaim-Defendants are also subject to personal jurisdiction in this judicial district because, upon information and belief, they sell products here and regularly practice business here.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), and (c), and 1400(b) and by Plaintiffs/Counterclaim-Defendants choice of forum.

BACKGROUND

7. Upon information and belief and based on paragraph 17 of the Counterclaim-Defendants' Complaint, Ingenus is the current sole owner of New Drug Application (NDA) No.

212501, which was approved by the U.S. Food and Drug Administration (FDA) for the sale and manufacture of Cyclophosphamide solution for intravenous use ("NDA Product").

8. Upon information and belief and based on paragraph 22 of the Counterclaim-Defendant's Complaint, Ingenus and Leiutis are the current assignees and owners of all right, title, and interest in the '952 patent.

9. Nexus filed ANDA No. 216783 ("Nexus's ANDA") with the FDA seeking approval to market cyclophosphamide injection ("Nexus's Proposed ANDA Product"), referencing NDA No. 212501.

10. As part of its ANDA, Nexus submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("a paragraph IV certification") that the '952 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Nexus's Proposed ANDA Product.

11. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), on or about April 21, 2022, Nexus sent by FedEx a letter concerning its paragraph IV certification (the "Notice Letter").

12. The Notice Letter included a detailed statement of the factual and legal bases for Nexus's opinion that the '952 patent is invalid, unenforceable, and/or not infringed by Nexus's Proposed ANDA Product. The Notice Letter included an Offer for Confidential Access.

13. Counterclaim-Defendants have actual knowledge of the contents of the Notice Letter.

14. On June 1, 2022, Counterclaim-Defendants filed the instant action in which Counterclaim-Defendant assert that Nexus's Proposed ANDA Product will infringe the '952 patent.

COUNTERCLAIM
(NON-INFRINGEMENT OF ANY VALID CLAIM OF THE '952 PATENT)

15. Nexus incorporates by reference the allegations set forth in each preceding paragraph of the Counterclaim as if fully set forth herein.

16. Actual and justiciable controversies exist between Nexus and Counterclaim-Defendants relating to the '952 patent.

17. A declaration of rights between the parties is both appropriate and necessary to establish that Nexus will not infringe any valid and enforceable claim of the '952 patent.

18. The commercial manufacture, use, offer for sale, sale, or importation of Nexus's Proposed ANDA Product has not infringed, does not infringe, and would not directly or indirectly infringe any valid and/or enforceable claim of the '952 patent, either literally or under the doctrine of equivalents, for at least the reasons Nexus presented in the Notice Letter, which is incorporated by reference.

19. Counterclaim-Defendants bear the burden of proving infringement and will not be able to meet that burden.

20. Nexus is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '952 patent.

21. All claims of the '952 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the Notice Letter.

22. As sufficient examples, as described in the Notice Letter, all claims of the '952 patent are at least invalid as obvious under § 103 in light of at least the following prior art: U.S. Patent No. 4,879,286 titled "Cyclophosphamide" ("Alam"); U.S. Patent Publication No. 2015/0320775 titled "Formulations of Cyclophosphamide Liquid Concentrate" ("Palepu"); PCT Patent Application Publication No. WO 02/021525 titled "Injectable Composition" ("Tait"); Shivakumar et al. (2015) Identification of Degradation Products in Cyclophosphamide API by LC-QTOF Mass Spectrometry, Journal of Liquid Chromatography & Related Technologies, 38:2, 190-195 (Oct. 10, 2014) ("Shivakumar"); and/or Nema et al., Excipients and Their Use in Injectable Products, *51 PDA J. PHARM. SCI. & TECH. 166* (1997) ("Nema").

23. Nexus is entitled to a declaration that the claims of the '952 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Nexus prays that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

A. A declaration that the claims of the ’952 patent are invalid;

B. A declaration that Nexus’s submission of ANDA No. No. 216783 seeking FDA approval to market a cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL and 1 mg/5 mL (200 mg/mL) has not infringed, and will not infringe, any valid claim of the ’952 patent;

C. A declaration that Nexus’s commercial manufacture, use, offer for sale, sale, or importation of the cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL and 1 mg/5 mL (200 mg/mL) that is the subject of ANDA No. 216783 will not infringe, induce infringement, or contribute to infringement of any valid claim of the ’952 patent;

D. A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Nexus;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Nexus its attorneys’ fees, costs and expenses;

F. A declaration that Counterclaim-Defendants are not entitled to injunctive relief;

G. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys and any person who acts in concert or

participation with Counterclaim-Defendants, from taking any action to unlawfully prevent the FDA approval of Nexus's ANDA No. 216783 and the product described therein;

H. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendants, from asserting or otherwise seeking to enforce the '952 patent against Nexus or anyone in privity with Nexus; and

I. Such other and further relief as the Court may deem proper.

DATED this 25th day of July, 2022.

/s/ *Joel M. Wallace*

Imron T. Aly (IL Bar No. 6269322)
Sailesh K. Patel (IL Bar No. 6270406)
Joel M. Wallace (IL Bar No. 6304223)
ARENTFOX SCHIFF LLP
233 South Wacker Drive
Suite 7100
Chicago, Illinois 60606
Tel.: (312) 258-5500
Fax: (312) 258-5600
imron.aly@afslaw.com
sailesh.patel@afslaw.com
Attorneys for Defendant and Counterclaim-Plaintiff Nexus Pharmaceuticals, Inc.