

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS,
LLC, and LEITIS
PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE INC.,

Defendant.

C.A. No. 23-377-CFC

**ACCORD HEALTHCARE, INC.’S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Accord Healthcare, Inc. (“Accord” or “Defendant”) responds to the Complaint by Plaintiffs Ingenus Pharmaceuticals, LLC and Leiutis Pharmaceuticals, LLP (collectively, “Plaintiffs”) 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, arising from Defendant’s submission of Abbreviated New Drug Application (“ANDA”) No. 218250 to the United States Food and Drug Administration (“FDA”). Defendant’s ANDA seeks FDA approval to market and sell Cyclophosphamide; 500mg/2.5ml (200mg/ml), 1gm/5ml (200mg/ml), 2gm/10ml (200mg/ml); and solution (“Defendant’s ANDA Products”) prior to the expiration of 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: Defendant admits that Plaintiffs purport to bring this action for alleged infringement of the ’952 Patent under the patent laws of the United States,

Title 35 of the United States Code. Defendant admits that it submitted ANDA No. 218250 in the name of Accord Healthcare, Inc. Defendant admits that a copy of the '952 Patent was attached to the complaint as Exhibit A. Defendant denies any remaining allegations in this paragraph.

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.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

3. 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: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

4. Upon information and belief, Accord is a corporation organized and existing under the laws of the State North Carolina, having a principal place of business at 1009 Slater Road, Suite 210 Durham, North Carolina 27703.

ANSWER: Admitted.

5. Upon information and belief, Accord 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 Delaware.

ANSWER: Defendant admits that Accord markets and distributes generic pharmaceutical products in the United States. Defendant denies any remaining allegations in this paragraph.

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

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

7. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.*, and alleges infringement of the '952 Patent.

ANSWER: Defendant admits that Plaintiffs purport to bring this action for alleged infringement of the '952 Patent under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.* Defendant denies any remaining allegations in this paragraph.

8. 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 8 states a legal conclusion to which no answer is required. To the extent an answer is required, Defendant admits that this court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. § § 1331, 1338(a), 2201, and 2202. Defendant denies any remaining allegations in this paragraph.

9. This Court has personal jurisdiction over Accord at least because, upon information and belief, Accord Healthcare, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Accord Healthcare, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendant's ANDA Products. Accord regularly does or solicits business in Delaware; engages in other persistent courses of conduct in Delaware; and/or derives substantial revenue from services or things used

or consumed in Delaware; thereby demonstrating that Accord has continuous and systematic contacts with Delaware.

ANSWER: Accord does not contest personal jurisdiction in this proceeding.

Accord denies any remaining allegations in this paragraph.

10. This Court has personal jurisdiction over Accord at least because, upon information and belief, Accord is the current owner of Abbreviated New Drug Application (ANDA) No. 218250 (“Accord’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 (200 mg/mL), 1 gm/5 mL (200 mg/mL), and 2 gm/10 mL (200 mg/mL) (“Accord’s ANDA Product” or “ANDA Product”), throughout the United States, including in Delaware, before the expiration of the ’952 Patent.

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant admits that Accord prepared and filed ANDA No. 218250 with the FDA. Defendant denies any remaining allegations in this paragraph.

11. This Court has personal jurisdiction over Accord at least because, upon information and belief, if Accord’s ANDA receives final approval, Accord’s ANDA Product will be manufactured, sold, distributed, and/or used by Accord in Delaware; prescribed by physicians practicing in Delaware; and/or administered to patients in Delaware.

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

12. Accord 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 February 20, 2023, sent by Accord Healthcare, 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. 218250 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

ANSWER: Denied.

13. On information and belief, Accord plans to sell its ANDA Product in the State of Delaware, list the ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

14. On information and belief, Accord intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of Plaintiffs' Cyclophosphamide Injection, causing injury to Ingenus and Leiutis. Accord intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

15. Accord Healthcare, 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., Celgene Corp. et al. v. Accord Healthcare Inc.*, No. 21-1795 (D. Del. Dec. 22, 2021); *Teva Pharmaceuticals International GmbH et al. v. Accord Healthcare Inc.*, No. 21-952 (D. Del. June 29, 2021); *Taiho Pharmaceutical Co., Ltd. et al. v. Accord Healthcare Inc. et al.*, No. 21-838 (D. Del. June 9, 2021); *Bayer Pharma AG et al. v. Accord Healthcare Inc. et al.*, No. 21-566 (D. Del. Apr. 22, 2021); *Purdue Pharma L.P. et al. v. Accord Healthcare Inc.*, No. 20-1362 (D. Del. Oct. 8, 2020); *Otsuka Pharmaceutical Co., Ltd. et al. v. Accord Healthcare Inc.*, No. 20-1287 (D. Del. Sep. 25, 2020); *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare Inc.*, No. 20-803 (D. Del. Jun. 12, 2020); *Merck Sharp & Dohme Corp. v. Accord Healthcare Inc. et al.*, No. 19-2192 (D. Del. Jan. 24, 2020); *Novartis Pharm. Co. v. Accord Healthcare Inc. et al.*, No. 18-1043 (D. Del. Aug. 8, 2018); *Amgen Inc. v. Accord Healthcare et al.*, No. 18-956 (D. Del. June 28, 2018)

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

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

ANSWER: Paragraph 16 states a legal conclusion to which no answer is required. To the extent an answer is required, Defendant does not contest venue in this proceeding. Defendant denies any remaining allegations in this paragraph.

17. Accord Healthcare, through their counsel, by email dated March 30, 2023, have consented to personal jurisdiction and venue in this Court for purposes of this matter, and have agreed that parent company Intas Pharmaceuticals will provide discovery as if it is a party to this matter.

ANSWER: Defendant admits that Defendant agreed not to contest personal jurisdiction and venue in this Court for purposes of this case only. Defendant admits that Defendant agreed that Intas Pharmaceuticals will provide discovery as if it is a party to this matter. Defendant denies any remaining allegations in this paragraph.

PLAINTIFFS' APPROVED DRUG PRODUCT AND U.S. PATENT

18. 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: Defendant admits that Defendant Cyclophosphamide solution is the subject of approved NDA No. 212501. Defendant lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

19. 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: Defendant admits that NDA No. 212501 is directed to Cyclophosphamide. Defendant lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

20. Plaintiffs' Cyclophosphamide NDA Product 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.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth the allegations in this paragraph, and therefore denies them.

21. 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: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies them.

22. 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: Defendant admits that the '952 Patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations." Defendant admits that the '952 patent states on its face that it was issued on May 4, 2021. Defendant denies any remaining allegations in this paragraph.

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

ANSWER: Defendant admits that Leiutis and Ingenus are listed as assignees

of record for the '952 Patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

24. 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: Defendant admits that the '952 Patent is listed in the Orange Book in connection with Cyclophosphamide Injection.

DEFENDANT'S ANDA NO. 218250

25. On information and belief, Defendant has submitted ANDA No. 218250 to FDA, or caused ANDA No. 218250 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: Defendant admits that Accord filed ANDA No. 218250 with a Paragraph IV certification with respect to the '952 Patent. Defendant denies any remaining allegations in this paragraph.

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

ANSWER: Admitted.

27. On information and belief, Accord sent Ingenus and Leiutis a Notice Letter dated February 20, 2023. The Notice Letter represents that Accord had submitted to FDA ANDA No. 218520 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: Defendant admits that that Accord Healthcare, Inc. sent a letter dated February 20, 2023 to Plaintiffs providing Notice of Paragraph IV Certification

with respect to Accord's ANDA No. 218250 and the '952 Patent. Defendant denies any remaining allegations in this paragraph.

28. On information and belief, Defendant seeks 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. 218250 with a Paragraph IV certification is to market the ANDA product described therein before the expiration of the '952 Patent.

ANSWER: Defendant admits that it filed ANDA No. 218250 with a Paragraph IV certification. Defendant denies any remaining allegations in this paragraph.

29. 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. 218250 for the ANDA Product is the treatment of malignant diseases as described in Plaintiffs' NDA.

ANSWER: Defendant admits that it filed ANDA No. 218250 with a Paragraph IV certification. Defendant denies any remaining allegations of this paragraph.

30. 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 Delaware, or will import the ANDA Product into the United States, including into the State of Delaware.

ANSWER: Defendant does not contest personal jurisdiction in this proceeding. Defendant denies any remaining allegations in this paragraph.

31. 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.

32. 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: Admitted.

FIRST COUNT
(Accord's Infringement of the '952 Patent)

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

ANSWER: Defendant incorporates its answers to each of the prior paragraphs.

34. Upon information and belief, Accord submitted or caused the submission of ANDA No. 218250 to FDA, seeking FDA approval of Defendant's ANDA.

ANSWER: Defendant admits that it filed ANDA No. 218250 with a Paragraph IV certification. Defendant denies any remaining allegations of this paragraph.

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

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

36. The ANDA Product falls within one or more claims of the '952 Patent.

ANSWER: Denied.

37. Accord does not contest infringement of any claims of the '952 Patent in its Notice Letter. If Accord had a factual or legal basis to contest infringement of any claims of the '952 Patent, Accord 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: Defendant admits that Accord filed ANDA No. 218250 with a Paragraph IV certification. Defendant denies any remaining allegations of this paragraph.

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

ANSWER: Denied.

39. 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).

ANSWER: Denied.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

RESPONSE TO PRAYER FOR RELIEF

Defendant denies that Plaintiffs are entitled to the requested relief or to any relief whatsoever.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The claims of the '952 Patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated February 20, 2023.

RESERVATION OF DEFENSES

Defendants reserve the right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

For its counterclaims against Plaintiffs Ingenus Pharmaceuticals, LLC ("Ingenus") and Leiutis Pharmaceuticals LLP ("Leiutis") (collectively, "Plaintiffs"), Defendant Accord Healthcare, Inc. ("Accord") states as follows:

THE PARTIES

1. Accord is a corporation organized under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210B, Durham, NC 27703.

2. On information and belief, 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.

3. On information and belief, 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

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. The Court has personal jurisdiction over Plaintiffs because Plaintiffs commenced and continue to maintain this action against Defendant in this judicial district.

7. Venue for these counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§1391(b)-(c) and 1400(b).

ACTS GIVING RISE TO THESE COUNTERCLAIMS

8. On May 4, 2021, the U.S. Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 10,993,952 (the ’952 patent), entitled “STABLE READY TO USE CYCLOPHOSPHAMIDE LIQUID FORMULATIONS.” Plaintiffs claim to be the owners of the ’952 patent by virtue of assignment.

9. On information and belief, Ingenus is indicated in the records of the U.S. Food and Drug Administration (“FDA”) as the holder of New Drug Application (“NDA”) No. 212501 for Cyclophosphamide Injection.

10. On information and belief, Ingenus submitted the ’952 Patent for listing in the electronic version of the FDA’s *Approved Drug Products with Therapeutic*

Equivalence Evaluations (“the Orange Book”) in connection with Cyclophosphamide Injection.

11. By letter dated February 20, 2023 (“Accord’s Notice Letter”), Accord Healthcare, Inc. notified Plaintiffs that it had filed Abbreviated New Drug Application (“ANDA”) No. 218250 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’952 Patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 218250 (“Accord’s ANDA Product”).

12. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Accord’s Notice Letter included a detailed statement of the factual and legal bases for the certification that the ’952 Patent is invalid, unenforceable, and/or will not be infringed by Accord’s ANDA Product.

13. Accord’s Notice Letter also included an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

14. On April 3, 2023, Plaintiffs filed suit against Accord, alleging infringement of the ’952 Patent.

FIRST CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’952 PATENT)

15. Defendant restates and realleges each of the foregoing paragraphs 1-14 as if fully set forth herein.

16. Plaintiffs have accused Defendant of infringing the ’952 Patent.

17. Defendant denies infringement of the ’952 Patent and alleges that the

claims of the '952 Patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

18. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '952 Patent.

19. Defendant is entitled to a judicial declaration that the claims of the '952 Patent are invalid under one or more of 35 U.S.C. § 101 *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Accord respectfully prays for judgment in its favor and against Plaintiffs:

(a) Declaring that each of the claims of the '952 Patent are invalid under one or more of 35 U.S.C. § 101 *et seq.*;

(b) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Defendant;

(c) Declaring this case exceptional and awarding Defendant its reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. § 285;

(d) Awarding Defendant such other relief as the Court may deem just and proper.

Dated: June 20, 2023

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