IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PIERRE FABRE DERMATOLOGIE; UNIVERSITÉ DE BORDEAUX; CENTRE HOSPITALIER UNIVERSITAIRE DE BORDEUAX; and PIERRE FABRE PHARMACEUTICALS, INC., *Plaintiffs,* v. ANNORA PHARMA PRIVATE LIMITED, *Defendant.*	C.A. No. 1:22-cv-01442-RGA

DEFENDANT'S ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Annora Pharma Private Limited ("Annora"), by its undersigned attorneys, hereby answer the Complaint for Patent Infringement (D.I. 1) ("Complaint") brought by Plaintiffs Pierre Fabre Dermatologie ("Pierre Fabre"), Unversité de Bordeaux ("Bordeaux"), Centre Hospitalier Universitaire de Bordeuax ("CHU"), and Pierre Fabre Pharmaceuticals, Inc. ("PFPI") (collectively, "Plaintiffs") concerning U.S. Patents Nos. 8,338,489 ("the '489 patent") and 8,987,262 ("the '262 patent) (collectively, "the Patents-in-Suit").

GENERAL DENIAL

Defendant denies all allegations in Plaintiffs' Complaint except for those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Defendant's own acts, and upon information and belief as to other matters, Defendant responds and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, U.S. Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 that arises out of Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 217567 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, and/or import versions of Pierre Fabre's HEMANGEOL® (Propranolol Hydrochloride) Solution; Oral, 4.28 MG/ML that is the subject of New Drug Application ("NDA") No. N205410 ("HEMANGEOL®") prior to the expiration of U.S. Patent Nos. 8,338,489 ("the '489 Patent") and 8,987,262 ("the '262 Patent") (together, the "Asserted Patents"). Plaintiffs seek all available relief under 35 U.S.C. § 100 *et seq.*, 28 U.S.C. §§ 2201 and 2202, and all other applicable laws for Annora's infringement of the Asserted Patents.

ANSWER: Annora admits that the above-captioned action purports to be an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, in response to Annora's submission of ANDA No. 217567 ("Annora's ANDA") to the United States Food and Drug Administration ("FDA"). Annora denies any remaining allegations contained in Paragraph 1.

2. Defendant notified Plaintiffs by letter dated September 19, 2022 ("Annora's Notice Letter") that it had submitted to the FDA ANDA No. 217567 ("Annora's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic propranolol hydrochloride solution for oral use ("Annora's ANDA Product") prior to the expiration of the asserted patents.

ANSWER: Paragraph 2 contains legal conclusions to which no response is required. To the extent a response is required, Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 2.

3. On information and belief, Annora's ANDA Product is a generic version of Plaintiff's HEMANGEOL® product.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 3.

THE PARTIES

4. Plaintiff Pierre Fabre is a French corporation having a principal place of business at 45 place Abel Gance, 92100 Boulegne Billancourt, France.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4, and therefore denies them.

5. Plaintiff Bordeaux is a French nonprofit Research and Educational Public Institution (Establissement Public à caractère Scientifue, Culterel et Professionnel) having a principal place of business at 35, Place Pey Berland, Bordeaux 33000 France.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5, and therefore denies them.

6. Plaintiff CHU is a French nonprofit Healthcare Public Institution (Establissement Public de Santé) having a principal place of business at 12 Rue Dubernat, Talence 33404, France.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6, and therefore denies them.

7. Plaintiff PFPI is a Delaware corporation having a principal place of business at 8 Campus Drive, Parsippany, New Jersey 07054.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7, and therefore denies them.

8. On information and belief, Defendant Annora is an Indian corporation, with a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist., Telangana State, 502313, India.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Annora admits that it is a corporation organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummandidala Mandal, Sangareddy Dist. Telgana State, 502313, India.

9. On information and belief, Annora's business includes developing, manufacturing, marketing, importing, and selling generic copies of innovator pharmaceutical products for the United States market.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 9.

JURISDICTION AND VENUE

10. This patent infringement action arises under the United States Patent Act, codified at Title 35, U.S. Code and as an action for declaratory judgment under 28 U.S.C. §§ 2201 and 2202 arising from Defendant's submission of Annora's ANDA.

ANSWER: Paragraph 10 contains allegations and/or conclusions of law to which no response is required. To the extent that a response is required, Annora admits that this actions arises under the patent laws of the United States of America. Annora denies any remaining allegations or legal conclusions contained in Paragraph 10.

11. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Relief is sought under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 11 contains allegations and/or conclusions of law to which no response is required. To the extent that a response is required, Annora admits only that, insofar as this action is properly brought, this Court has subject matter jurisdiction to adjudicate this action. Annora denies any remaining allegations or legal conclusions contained in Paragraph 11.

12. This Court has personal jurisdiction over Annora because, on information and belief, Annora maintains persistent and continuous contacts with Delaware and has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably

anticipate being haled into court here. On information and belief, Annora regularly and continuously develops, manufactures, markets, and/or sells generic pharmaceutical products in Delaware and derives substantial revenue from the sale of those products in Delaware. Annora has also regularly engaged in litigation concerning FDA-approved products in this District, has not contested personal jurisdiction in such matters, and has purposefully availed itself of the benefits of this District by asserting claims and/or counterclaims in this Court, including in such cases as: *Silvergate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, C.A. No. 20-753-LPS (D. Del.); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd*., C.A. No. 20-277-CFC (D. Del.); *Amgen Inc. v. Annora Pharma Private Ltd*., C.A. No. 20-122-CFC (D. Del.); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd*., C.A. No. 18-1996-MN (D. Del.); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd*., C.A. No. 18-1786-CFC-SRF (D. Del.).

ANSWER: Paragraph 12 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora does not contest personal jurisdiction in this case the purposes of this action only. Annora denies any remaining allegations or legal conclusions in Paragraph 12.

13. Additionally, on information and belief, Delaware is a likely destination of the product that is the subject of ANDA No. 217567.

ANSWER: Paragraph 13 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora does not contest personal jurisdiction in this case for the purposes of this action only. Annora denies any remaining allegations or legal conclusions in Paragraph 13.

14. Alternatively, this Court has personal jurisdiction over Annora under FED. R. CIV. P. 4(k)(2) because Plaintiffs' claims arise under federal law; Annora is a foreign defendant not subject to personal jurisdiction in the courts of any state; and Annora has sufficient contacts with the United States as a whole, including at least preparing and submitting ANDA No. 217567 to the FDA and manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Annora satisfies due process.

ANSWER: Paragraph 14 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora does not contest personal jurisdiction in this case for the purposes of this action only. Annora denies any remaining allegations or legal conclusions in Paragraph 14.

15. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c) because Annora is a foreign corporation not residing in any state and therefore may be sued in any judicial district having personal jurisdiction over Annora.

ANSWER: Paragraph 15 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora does not contest venue in this Court for the purposes of this action only. Annora denies any remaining allegations or legal conclusions in Paragraph 15

PIERRE FABRE'S HEMANGEOL PRODUCT

16. Pierre Fabre is the holder of NDA No. N205410.

ANSWER: Paragraph 16 contained allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora admits that the electronic version of FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") lists "Pierre Fabre Dermatologie" as the applicant holder of NDA No. N205410. Annora lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 16, and therefore denies them.

17. Pierre Fabre's HEMANGEOL®, covered by NDA No. N205410, is the only FDA approved treatment for infantile hemangioma requiring systemic therapy.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17, and therefore denies them.

18. PFPI is exclusively responsible for sales of HEMANGEOL® in the United States.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 18, and therefore denies them.

19. Plaintiffs Bordeaux and CHU are the assignees of all rights from the named inventors to the Asserted Patents, as reflected in the assignments recorded at Reel 024381, Frame 0618; Reel 033025, Frame 0790; Reel 033025, Frame 0881; and Reel 029684, Frame 0737.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19, and therefore denies them.

20. Pierre Fabre is the exclusive licensee to all rights under the Asserted Patents, as reflected in documents recorded at Reel 040517, Frame 0767 and Reel 040815, Frame 0172.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20, and therefore denies them.

THE ASSERTED PATENTS

21. On November 6, 2009, Christine Leaute-Labreze, Eric Dumas De La Roque, Alain Taieb, and Jean-Benoit Thambo ("the Inventors") filed U.S. Patent Application No. 12/599,266 ("the '266 Application") entitled "Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas."

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21, and therefore denies them.

22. The '266 Application is the national stage entry into the United States of PCT Patent Application No. PCT/IB2008/002746, filed on October 16, 2008 and claims priority to Provisional Patent Application No. 60/989,507, filed on November 21, 2007; and European Patent Application No. 07291723.6, filed on October 19, 2007.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22, and therefore denies them

23. On December 25, 2012, the '489 Patent was issued by the PTO based on the '266 Application. A true and correct copy of the '489 Patent is attached hereto as Exhibit A and is incorporated by reference as if fully set forth herein.

ANSWER: Annora admits that on its face, the '489 patent titled "Use of beta blocker for the manufacture of a medicament for the treatment of hemangiomas" issued on December 25, 2012. Annora lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 23, and therefore denies them.

24. On November 16, 2012, the Inventors filed U.S. Patent Application No. 13/678,802 ("the '802 Application") entitled "Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas."

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 24, and therefore denies them.

25. The '802 Application was filed as a continuation-in-part of the '266 Application, which was filed as the national stage entry of PCT Patent Application No. PCT/IB2008/002746, filed on October 16, 2008, and further claims priority to Provisional Patent Application No. 60/989,507, filed on November 21, 2007; and European Patent Application No. 07291723.6, filed on October 19, 2007.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25, and therefore denies them.

26. On March 24, 2015, the '262 Patent was issued by the PTO based on the '802 Application. A true and correct copy of the '262 Patent is attached hereto as Exhibit B and is incorporated by reference as if fully set forth herein.

ANSWER: Annora admits that on its face, the '262 patent titled "Use of beta blocker for the manufacture of a medicament for the treatment of hemangiomas" issued on March 24, 2015. Annora lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 26, and therefore denies them.

27. The Asserted Patents are valid and enforceable.

ANSWER: Denied.

28. Pursuant to 21 U.S.C. § 355, the Asserted Patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. N205410, sold under the brand name HEMANGEOL®.

ANSWER: Paragraph 28 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora admits that the Asserted Patents remain listed in the Orange Book for NDA No. N205410 for HEMANGEOL®.

29. Pierre Fabre's HEMANGEOL® product is covered by at least one claim of each of the Asserted patents.

ANSWER: Paragraph 29 contains allegations and/or conclusions of law to which no response is required, and therefore denies them.

30. Plaintiff Pierre Fabre possesses all rights of recovery under the Asserted Patents, including the right to sue for infringement, recourse for damages, and to seek injunctive relief.

ANSWER: Annora lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30, and therefore denies them.

INFRINGEMENT BY ANNORA

31. In Annora's Notice Letter, Annora notified Pierre Fabre, Bordeaux, CHU, and Pierre Fabre S.A. that it had submitted ANDA No. 217567 to the FDA pursuant to subsection 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("the FDCA") (21 U.S.C. § 355(j)(2)(B)(ii)) to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Pierre Fabre's HEMANGEOL® product, Annora's ANDA Product, before the expiration of the Asserted Patents.

ANSWER: Admitted.

32. The Asserted Patents will expire shortly after midnight on October 16, 2028.

ANSWER: Paragraph 32 contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Annora admits that the Orange Book provides October 16, 2028 as the expiration dates for the Asserted Patents.

33. On information and belief, Annora intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Annora ANDA Product promptly upon receiving FDA approval to do so.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 33.

34. Annora is seeking approval from the FDA to engage in the commercial manufacture, use, and sale of the Annora ANDA Product before the expiration of the Asserted Patents.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 34.

35. By submitting ANDA No. 217567, Annora necessarily represented to the FDA that Annora's ANDA Product has the same active ingredients as Pierre Fabre's HEMANGEOL® product; has the same route of administration, dosage form, use, and strength as Pierre Fabre's HEMANGEOL® product; and is bioequivalent to Pierre Fabre's HEMANGEOL® product.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 35.

COUNT 1 – INFRINGEMENT OF THE '489 PATENT

36. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 of this Complaint as if fully set forth herein.

ANSWER: Annora repeats and realleges its Answers to the allegations in paragraphs 1 through 35 as if fully set forth herein.

37. Annora submitted or caused the submission of ANDA No. 217567 to the FDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import Annora's ANDA Product throughout the United States before the expiration of the '489 Patent.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 37.

38. Annora's ANDA Product is covered by one or more claims of the '489 Patent.

ANSWER: Denied.

39. By submitting ANDA No. 217567, Annora committed an act of infringement of one or more claims of the '489 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

40. The claims infringed by Annora's ANDA Product include at least Claim 1 of the '489 Patent.

ANSWER: Denied.

41. If ANDA No. 217567 is approved, Annora's commercial manufacture, use, offering for sale, sale, and/or importation of Annora's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '489 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

ANSWER: Denied.

42. If ANDA No. 217567 is approved, Annora will induce infringement of one or more claims of the '489 Patent under 35 U.S.C. § 271(b) by causing third parties to manufacture, use, offer for sale, sell, and/or import Annora's ANDA Product into the United States and will intentionally encourage acts of direct infringement with knowledge of the '489 Patent and knowledge that such acts are infringing, unless enjoined by the Court.

ANSWER: Denied.

43. If ANDA No. 217567 is approved, Annora will contributorily infringe one or more claims of the '489 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Product into the United States, unless enjoined by this Court. On information and belief, Annora has had and continues to have knowledge that the Annora ANDA Product is especially adapted for a use that infringes one or more claims of the '489 Patent and that there is no substantial noninfringing use for the Annora ANDA Product.

ANSWER: Denied.

44. As a result of Annora's infringement of the '489 Patent, Plaintiffs will be damaged to an extent not yet determined and will be caused further irreparable harm for which damages are inadequate.

ANSWER: Denied.

COUNT II - INFRINGEMENT OF THE '262 PATENT

45. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 [sic] of this Complaint as if fully set forth herein.

ANSWER: Annora repeats and realleges its Answers to the allegations in paragraphs 1 through 44 as if fully set forth herein.

46. Annora submitted or caused the submission of ANDA No. 217567 to the FDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import Annora's ANDA Product throughout the United States before the expiration of the '262 Patent.

ANSWER: Annora admits that it filed ANDA No. 217567 with the FDA to obtain approval for the commercial manufacture and sale in the United States of propranolol hydrochloride solution, 4.28 MG/ML. Annora denies any remaining allegations in Paragraph 46.

47. Annora's ANDA Product is covered by one or more claims of the '262 Patent.

ANSWER: Denied.

48. By submitting ANDA No. 217567, Annora committed an act of infringement of one or more claims of the '262 Patent under 35 U.S.C. § 271(e)(2)(A). The infringed claims include at least Claim 1 of the '262 Patent.

ANSWER: Denied.

49. If ANDA No. 217567 is approved, Annora's commercial manufacture, use, offering for sale, sale, and/or importation of Annora's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '262 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

ANSWER: Denied.

50. If ANDA No. 217567 is approved, Annora will induce infringement of one or more claims of the '262 Patent under 35 U.S.C. § 271(b) by causing third parties to manufacture, use, offer for sale, sell, and/or import Annora's ANDA Product into the United States and will intentionally encourage acts of direct infringement with knowledge of the '262 Patent and knowledge that such acts are infringing, unless enjoined by the Court.

ANSWER: Denied.

51. If ANDA No. 217567 is approved, Annora will contributorily infringe one or more claims of the '262 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Product into the United States, unless enjoined by this Court. On information and belief, Annora has had and continues to have knowledge that Annora's ANDA Product is especially adapted for a use that infringes one or more claims of the '489 Patent and that there is no substantial noninfringing use for Annora's ANDA Product.

ANSWER: Denied.

52. As a result of Annora's infringement of the '262 Patent, Plaintiffs will be damaged to an extent not yet determined and will be caused further irreparable harm for which damages are inadequate.

ANSWER: Denied.

COUNT III – DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '489 PATENT

53. Plaintiffs reallege and incorporate by reference paragraphs 1 through 44 [sic] of this Complaint as if fully set forth herein.

ANSWER: Annora repeats and realleges it Answers to the allegations in paragraphs 1 through 52 as if fully set forth herein.

54. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between the Plaintiffs and Annora regarding Annora's infringement, active inducement of infringement, and contribution to the infringement by others of the '489 Patent.

ANSWER: Paragraph 54 contains allegations and/or conclusions of law to which no response is required, and therefore denies them.

55. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Annora's ANDA Product, or any other Annora drug product that is covered by or the use of which is covered by the '489 Patent, will infringe, induce infringement of, and contribute to the infringement by others of the '489 Patent, and that the claims of the '489 Patent are valid.

ANSWER: Denied.

COUNT IV – DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '262 PATENT

56. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 and 45 through 52 of this Complaint as if fully set forth herein

ANSWER: Annora repeats and realleges its Answers to the allegations in paragraphs 1 through 55 as if fully set forth herein

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between the Plaintiffs and Annora regarding Annora's infringement, active inducement of infringement, and contribution to the infringement by others of the '262 Patent.

ANSWER: Paragraph 57 contains allegations and/or conclusions of law to which no response is required, and therefore denies them.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Annora's ANDA Product, or any other Annora drug product that is covered by or the use of which is covered by the '262 Patent, will infringe, induce infringement of, and contribute to the infringement by others of the '262 Patent, and that the claims of the '262 Patent are valid.

ANSWER: Denied.

PRAYER FOR RELIEF

Annora denies that Plaintiffs are entitled to any judgment or relief against Annora and, therefore, specifically denies Paragraphs (a)-(h) of the Complaint's Prayer for Relief. Each averment and/or allegation contained in Plaintiffs' Complaint that is not specifically admitted herein is hereby denied. Annora requests that judgment be entered in its favor, dismissing Plaintiffs' Complaint with prejudice, awarding Annora's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and

proper.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiff's Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Annora avers and asserts the following Affirmative Defenses to the Complaint. Annora expressly reserve the right to allege additional defenses as they become known through the course of discovery.

FIRST DEFENSE
Failure to State a Claim

Plaintiffs fail to state a claim upon which relief can be granted.

SECOND DEFENSE
Non-Infringement of the '489 Patent

Annora has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '489 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Annora's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '489 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

THIRD DEFENSE
Invalidity of the '489 Patent

Each claim of the '489 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FOURTH DEFENSE
Non-Infringement of the ’262 Patent

Annora has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the ’262 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Annora’s ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the ’262 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FIFTH DEFENSE
Invalidity of the ’262 Patent

Each claim of the ’262 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

SIXTH DEFENSE
No Exceptional Case

Annora’s actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE
No Willful Infringement

Annora has not willfully infringed any valid and enforceable claim of the Patents-in-Suit.

EIGHTH DEFENSE

Any defense asserted in any other action in which the Patents-in-Suit are asserted that may be asserted in this action.

RESERVATION OF DEFENSES

Annora reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

Dated: December 27, 2022

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