IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARMONY BIOSCIENCES, LLC, BIOPROJET SOCIÉTÉ CIVILE DE RECHERCHE and BIOPROJET PHARMA SAS, *Plaintiffs*, v. AET PHARMA US, INC., ANNORA PHARMA PRIVATE LIMITED, NOVITIUM PHARMA LLC, ZENARA PHARMA PRIVATE LIMITED and BIOPHORE INDIA PHARMACEUTICALS PRIVATE LIMITED, *Defendants.*	C.A. No. 1:23-cv-01340-JLH

DEFENDANT ANNORA PHARMA PRIVATE LIMITED'S ANSWER TO PLAINTIFFS' COMPLAINT WITH AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Annora Pharma Private Limited ("Annora" or "Defendant Annora"), through its attorneys, hereby answers the Complaint of Plaintiffs Harmony Biosciences, LLC ("Harmony"), Bioprojet Société Civile de Recherche ("Bioprojet SCR"), and Bioprojet Pharma SAS ("Bioprojet Pharma") (collectively, "Plaintiffs") and assert affirmative defenses and counterclaims as follows[1]:

[1] Defendants Hetero USA Inc. and Hetero Labs Limited ("the former Hetero Defendants") have been dismissed from this case, and the case caption ordered amended to reflect the dismissal. *See* Dkt. Nos. 16, 17 (Stipulation and [Proposed] Order Dismissing Defendants Hetero USA, Inc. and Hetero Labs Limited Without Prejudice and Amending Caption to Reflect Same (Dec. 27, 2023); and Order (Jan. 2, 2024)). This Answer and Counterclaims is being filed on behalf of Defendant Annora only. "Defendant Annora" shall be understood to mean only Defendant Annora Pharma Private Limited, regardless of the definitions set forth in the Complaint.

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., arises from AET's, Annora's, Novitium's, and Zenara's recent submission of Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA"), seeking approval to market generic versions of the pharmaceutical product WAKIX® (pitolisant hydrochloride) tablets prior to the expiration of U.S. Patent Nos. 8,486,947 ("the '947 patent"); 8,207,197 ("the '197 patent"); and/or 8,354,430 ("the '430 patent) (collectively, "the patents-in-suit").

ANSWER: Defendant Annora admits that Plaintiffs' complaint purports to set forth an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1. Defendant Annora admits that Hetero USA submitted an ANDA to the FDA, on behalf of Annora, seeking approval for Pitolisant Tablets 4.45 mg and 17.8 mg tablets ("Proposed ANDA Products") before the expiration of United States Patent Nos. 8,486,947 ("the '947 patent"); 8,207,197 ("the '197 patent"); and/or 8,354,430 ("the '430 patent) (collectively, "the Patents-in-Suit"). Defendant Annora denies any remaining allegations in Paragraph 1.

WAKIX® AND THE PATENTS-IN-SUIT

2. WAKIX® is a first-in-class drug indicated for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adult patients with narcolepsy.

ANSWER: Defendant Annora admits that WAKIX® is indicated for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adult patients with narcolepsy. Defendant Annora is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 2, and therefore denies the same.

3. Narcolepsy is a debilitating disease that can severely affect a patient's day-to-day functioning and can have a devastating impact on quality of life.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3, and therefore denies the same.

4. WAKIX®'s active ingredient, pitolisant hydrochloride, is an antagonist/inverse agonist of the histamine-3 (H3) receptor.

ANSWER: Defendant Annora admits the allegations of Paragraph 4.

5. WAKIX® first received FDA approval on August 14, 2019. It is the first FDA-approved H3 receptor antagonist/inverse agonist and the first and only FDA-approved once-daily tablet for treatment of EDS and cataplexy in narcolepsy. It is the only FDA-approved treatment for EDS and cataplexy in narcolepsy that is not a scheduled controlled substance.

ANSWER: Defendant Annora admits that WAKIX® first received FDA approval on August 14, 2019, and that it is indicated for the treatment of EDS or cataplexy in adult patients with narcolepsy. Defendant Annora lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5, and therefore denies the same.

6. WAKIX® was granted orphan drug exclusivity for the treatment of excessive daytime sleepiness in adult patients with narcolepsy and for the treatment of cataplexy in adult patients with narcolepsy; fast track designation for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy; and breakthrough therapy designation for the treatment of cataplexy in people with narcolepsy.

ANSWER: Defendant Annora admits that WAKIX® was granted orphan drug exclusivity for the treatment of excessive daytime sleepiness in adult patients with narcolepsy and for the treatment of cataplexy in adult patients with narcolepsy. Defendant Annora lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6, and therefore denies the same.

7. WAKIX® is available in film-coated tablets containing 5 mg or 20 mg of pitolisant hydrochloride (equivalent to 4.45 mg or 17.8 mg of pitolisant free base, respectively).

ANSWER: Defendant Annora admits the allegations in Paragraph 7.

8. The '947 patent is entitled "Treatment of Parkinson's Disease, Obstructive Sleep Apnea, Dementia with Lewy Bodies, Vascular Dementia with Non-Imidazole Alkylamines Histamine H3-Receptor Ligands," and was duly and lawfully issued by the USPTO on July 16, 2013. The '947 patent is attached hereto as Exhibit A.

ANSWER: Defendant Annora admits that the '947 patent is entitled "Treatment of Parkinson's Disease, Obstructive Sleep Apnea, Dementia with Lewy Bodies, Vascular Dementia

with Non-Imidazole Alkylamines Histamine H3-Receptor Ligands," and that it issued on July 16, 2013. Defendant Annora admits that Exhibit A attached to the Complaint appears to be a copy of the '947 patent. Defendant Annora denies any remaining allegations in Paragraph 8.

9. The '197 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and was duly and lawfully issued by the USPTO on June 26, 2012. The '197 patent is attached hereto as Exhibit B.

ANSWER: Defendant Annora admits that the '197 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and that it issued on June 26, 2012. Defendant Annora admits that Exhibit B attached to the Complaint appears to be a copy of the '197 patent. Defendant Annora denies any remaining allegations in Paragraph 9.

10. The '430 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and was duly and lawfully issued by the USPTO on January 15, 2013. The '430 patent is attached hereto as Exhibit C.

ANSWER: Defendant Annora admits that the '430 patent is entitled "Monohydrochloride Salt of 1-[3-[3-(4-Chlorophenyl) Propoxy]Propyl] -Piperidine," and that it issued on January 15, 2013. Defendant Annora admits that Exhibit C attached to the Complaint appears to be a copy of the '430 patent. Defendant Annora denies any remaining allegations in Paragraph 10.

11. The '947, '197, and '430 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for WAKIX®.

ANSWER: Defendant Annora admits that the '947, '197, and '430 patents are listed in the Orange Book in connection with WAKIX®.

PARTIES

12. Plaintiff Harmony Biosciences, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 630 W Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, USA. Harmony is the exclusive licensee of the patents-in-suit and the holder of New Drug Application ("NDA") No. 211150 for WAKIX®.

Harmony is engaged in the clinical development of WAKIX® and sells WAKIX® tablets in the United States.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 12, and therefore denies them.

13. Plaintiff Bioprojet SCR is an independent, privately owned company organized and existing under the laws of France, having a place of business at 7, rue Rameau, 75002, Paris, France. Bioprojet SCR is the assignee and owner of the patents-in-suit.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 13, and therefore denies them.

14. Plaintiff Bioprojet Pharma is a wholly owned subsidiary of Bioprojet SCR, existing under the laws of France, having a place of business at 9, rue Rameau, 75002, Paris, France. Bioprojet Pharma was involved in commercialization efforts.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 14, and therefore denies them.

15. On information and belief, Defendant AET Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9841 Washingtonian Boulevard, Suite 200, Gaithersburg, Maryland 20878.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 15, and therefore denies them.

16. On information and belief, AET caused ANDA No. 218892 ("AET ANDA") to be submitted to FDA and seeks approval of that application to permit AET to market generic versions of WAKIX® tablets in the United States.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 16, and therefore denies them.

17. On information and belief, AET intends to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218892 ("AET ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the AET ANDA.

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

18. On information and belief, Defendant Annora Pharma Private Limited is a corporation organized and existing under the laws of the Republic of India, having a principal place of business in Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State, 502313, India.

ANSWER: Defendant Annora admits that Annora Pharma Private Limited is a company organized and existing under the laws of the Republic of India, having a principal place of business in Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State, 502313, India.

19. On information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018, Telangana, India.

ANSWER: Paragraph 19 relates to Defendant Hetero Labs Limited, which has been dismissed from the case. (Dkt Nos. 16, 17). No response is required from Defendant Annora.

20. On information and belief, Hetero Labs Limited is the parent company of Defendants Annora Pharma Private Limited and Hetero USA, Inc.

ANSWER: Defendant Annora admits that Hetero USA, Inc. and Defendant Annora are subsidiaries of Hetero Labs Limited.

21. On information and belief, Hetero Labs Limited ultimately owns all of Annora's ANDAs, including ANDA No. 218832.

ANSWER: Admitted.

22. On information and belief, Defendant Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Paragraph 22 relates to Defendant Hetero USA, Inc., which has been dismissed from the case. (Dkt Nos. 16, 17). No response is required from Defendant Annora.

23. On information and belief, Hetero USA, Inc. serves as the U.S. agent for Annora Pharma Private Limited and Hetero Labs Limited. By letter dated October 16, 2023 ("Annora's Notice Letter"), Annora Pharma Private Limited, identified Dr. Somaraju Indukuri of Grace Consulting Services, Inc. in Piscataway, New Jersey, as its U.S. agent and the person authorized to accept service of process for any patent infringement complaint that may result from Annora's

Notice Letter. On information and belief, Somaraju Indukuri has held the position of Vice President of Regulatory Affairs at and has served as U.S. Agent for Hetero USA, Inc. from October 2016 to the present.

ANSWER: Defendant Annora denies that Hetero USA, Inc. serves as U.S. agent for any entity with regard to Annora's Notice Letter. Defendant Annora admits that Annora's Notice Letter identified Dr. Somaraju Indukuri, Ph.D., U.S. Agent for Grace Consulting Services, Inc., 121 New England Avenue, Piscataway, New Jersey 08854, as "authorized to accept service of process for any patent infringement complaint that may result from this notification (and limited to such a complaint only)." Defendant Annora lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 23, and therefore denies them.

24. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

ANSWER: Defendant Annora admits that Hetero USA, Inc. and Defendant Annora are subsidiaries of Hetero Labs Limited. Defendant Annora otherwise denies the allegations of Paragraph 24.

25. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited caused ANDA No. 218832 ("Annora ANDA") to be submitted to FDA and seek approval of that application to permit them to market generic versions of WAKIX® tablets in the United States.

ANSWER: Defendant Annora admits that Grace Consulting Services submitted ANDA No. 218832 on behalf of Annora Pharma Private Limited, seeking approval for the Proposed ANDA Products. Defendant Annora otherwise denies the remaining allegations in Paragraph 25.

26. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited acted collaboratively in the preparation and submission of ANDA No. 218832 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218832 and

seeking to market the proposed generic pitolisant hydrochloride tablets described in that application.

ANSWER: Denied.

27. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited intend to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218832 ("Annora ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the Annora ANDA.

ANSWER: Denied.

28. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited rely on material assistance from each other to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the Annora ANDA Products, in the event FDA approves the Annora ANDA.

ANSWER: Denied.

29. On information and belief, Defendant Novitium Pharma LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 70 Lake Drive, East Windsor, New Jersey 08520.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

30. On information and belief, Novitium Pharma LLC caused ANDA No. 218495 ("Novitium ANDA") to be submitted to FDA and seeks approval of that application to permit Novitium to market generic versions of WAKIX® tablets in the United States.

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

31. On information and belief, Novitium intends to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218495 ("Novitium ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 31, and therefore denies them.

32. On information and belief, Defendant Zenara Pharma Private Limited is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at Plot 87-96, Phase III, Industrial Development Area, Cherlapally, Hyderabad, 500051, India.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 32, and therefore denies them.

33. On information and belief, Biophore India Pharmaceuticals Private Limited is a corporation existing under the laws of the Republic of India, having its principal place of business at Plot 92; 1-98/2/92, Kavuri Hills – Phase II, Jubilee Hills, Hyderabad, 500033, Telangana, India.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 33, and therefore denies them.

34. On information and belief, Biophore India Pharmaceuticals Private Limited is the parent company of Zenara Pharma Private Limited.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 34, and therefore denies them.

35. On information and belief, Biophore India Pharmaceuticals Private Limited ultimately owns all of Zenara Pharma Private Limited's ANDAs, including ANDA No. 218796.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 35, and therefore denies them.

36. On information and belief, Biophore India Pharmaceuticals Private Limited owns Drug Master File No. 37753 for pitolisant hydrochloride.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 36, and therefore denies them.

37. On information and belief, Zenara Pharma Private Limited acts at the direction, and for the benefit, of Biophore India Pharmaceuticals Private Limited, and is controlled and/or dominated by Biophore India Pharmaceuticals Private Limited.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 37, and therefore denies them.

38. Biophore India Pharmaceuticals Private Limited and Zenara Pharma Private Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, Biophore India Pharmaceuticals Private Limited and Zenara Pharma Private Limited are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 38, and therefore denies them.

39. On information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited caused ANDA No. 218796 ("Zenara ANDA") to be submitted to FDA and seek approval of that application to permit Zenara to market generic versions of WAKIX® tablets in the United States.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 39, and therefore denies them.

40. On information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited acted collaboratively in the preparation and submission of ANDA No. 218796 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218796 and seeking to market the proposed generic pitolisant hydrochloride tablets described in that application.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 40, and therefore denies them.

41. On information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited intend to commercially manufacture, market, offer for sale, and sell the products described in ANDA No. 218796 ("Zenara ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 41, and therefore denies them.

42. On information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited rely on material assistance from each other to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited intend to act collaboratively to commercially manufacture, market, distribute,

offer for sale, and/or sell the Zenara ANDA Products, in the event FDA approves the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 42, and therefore denies them.

JURISDICTION AND VENUE

43. 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 patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

ANSWER: Paragraph 43 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that Plaintiffs' complaint purports to set forth an action for patent infringement under 35 U.S.C. § 271. Further, Defendant Annora admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a) for claims under 35 U.S.C. § 271 relating to ANDA No. 218832 only. Defendant Annora denies any remaining allegations in Paragraph 43, and states that joinder of the Defendants named in the Complaint within a single case is improper, and reserves its rights in that regard.

AET

44. This Court has personal jurisdiction over AET Pharma US, Inc. because it is a corporation organized and existing under the laws of the State of Delaware. AET Pharma US, Inc. is registered to do business as a domestic corporation in Delaware (File Number 5467023).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 44, and therefore denies them.

45. Additionally, this Court has personal jurisdiction over AET because, on information and belief, AET, inter alia, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell the AET ANDA Products in the State of Delaware upon approval of the AET ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 45, and therefore denies them.

46. On information and belief, AET is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, throughout the United States, including in Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 46, and therefore denies them.

47. On information and belief, AET is licensed to sell pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 47, and therefore denies them.

48. AET has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of one or more of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated October 14, 2023, sent by AET Pharma US, Inc. to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("AET's Notice Letter"), AET prepared and filed the AET ANDA with the intention of seeking to market the AET ANDA Products nationwide, including in Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 48, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 49, and therefore denies them.

50. On information and belief, AET knows and intends that the AET ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. AET intends to take advantage of its established channels of distribution in Delaware for the sale of the AET ANDA Products.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 50, and therefore denies them.

51. Venue is proper in this district for AET pursuant to 28 U.S.C. § 1400(b) because, inter alia, it is a corporation organized and existing under the laws of the State of Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 51, and therefore denies them.

Annora

52. This Court has personal jurisdiction over Hetero USA, Inc. because it is a corporation organized and existing under the laws of Delaware. Hetero USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 4837317).

ANSWER: Paragraph 52 relates to Defendant Hetero USA, Inc., which has been dismissed from the case. (Dkt Nos. 16, 17). No response is required from Defendant Annora.

53. Additionally, this Court has personal jurisdiction over Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited (collectively "Annora") because, on information and belief, Annora, inter alia, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell the Annora ANDA Products in the State of Delaware upon approval of the Annora ANDA.

ANSWER: Paragraph 53 includes allegations as to Defendants Hetero USA, Inc. and Hetero Labs Limited, which have been dismissed from the case, and no response is required from Defendant Annora on behalf of the dismissed entities. (Dkt. Nos. 16, 17). Responding on behalf of Defendant Annora only, denied. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

54. On information and belief, Annora is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, throughout the United States, including in Delaware.

ANSWER: Defendant Annora admits that Annora has sought approval for the manufacture, use, or sale of the Proposed ANDA products. Defendant Annora denies any remaining allegations in Paragraph 54. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

55. On information and belief, Annora is licensed to sell pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

56. Annora has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated October 16, 2023, sent by Annora Pharma Private Limited to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("Annora's Notice Letter"), Annora prepared and filed the Annora ANDA with the intention of seeking to market the Annora ANDA Products nationwide, including within Delaware.

ANSWER: Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product. Defendant Annora denies the remaining allegations in Paragraph 56. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

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

ANSWER: Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

58. On information and belief, Annora knows and intends that the Annora ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. Annora intends to take advantage of its established channels of distribution in Delaware for the sale of the Annora ANDA Products.

ANSWER: Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product. Defendant

Annora denies the remaining allegations in Paragraph 58. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

59. Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited have engaged in patent litigation concerning FDA-approved drug products in Delaware and have not contested personal jurisdiction or venue in Delaware in such litigation. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-277-CFC, D.I. 8 (D. Del. Apr. 27, 2020); *Amgen Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-122-CFC, D.I. 9 (D. Del. Mar. 26, 2020); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 18-1786-CFC-SRF, D.I. 19 (D. Del. Jan. 18, 2019); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd.*, C.A. No. 18-1996-MN, D.I. 12 (D. Del. Mar. 1, 2019).

ANSWER: Paragraph 59 includes allegations as to Defendants Hetero USA, Inc., and Hetero Labs Limited, that have been dismissed from the case, and no response is required from Defendant Annora on behalf of the dismissed entities. (Dkt. Nos. 16, 17). Responding on behalf of Defendant Annora only, Defendant Annora admits that it has been a party to the cases identified in Paragraph 59 and does not contest personal jurisdiction for the purposes of this action only.

60. Alternatively, this Court has personal jurisdiction over Annora Pharma Private Limited and Hetero Labs Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) each is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) each has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Annora ANDA, and/or manufacturing and/or selling pharmaceutical products throughout the United States including in Delaware, such that this Court's exercise of jurisdiction over Annora Pharma Private Limited and Hetero Labs Limited satisfies due process.

ANSWER: Paragraph 60 includes allegations as to Defendant Hetero Labs Limited, that has been dismissed from the case, and no response is required from Defendant Annora on behalf of a dismissed entity. (Dkt. Nos. 16, 17). Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product. Defendant Annora denies the remaining allegations in Paragraph 60. Defendant Annora does not contest personal jurisdiction for the purposes of this action only.

61. Venue is proper in this district for Hetero USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, inter alia, it is a corporation organized and existing under the laws of the State of Delaware.

ANSWER: Paragraph 61 includes allegations as to Defendant Hetero USA, Inc. that has been dismissed from the case, and no response is required from Defendant Annora on behalf of a dismissed entity. (Dkt. Nos. 16, 17).

62. Venue is proper in this district for Annora Pharma Private Limited and Hetero Labs Limited pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, inter alia, each is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district, and is subject to personal jurisdiction in Delaware.

ANSWER: Paragraph 62 includes allegations as to Defendant Hetero Labs Limited, that has been dismissed from the case, and no response is required from Defendant Annora on behalf of a dismissed entity. (Dkt. Nos. 16, 17). Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that Annora Pharma Private Limited is a corporation organized and existing under the laws of the Republic of India. Defendant Annora denies the remaining allegations in Paragraph 62. Defendant Annora does not contest venue for the purposes of this action only.

Novitium

63. This Court has personal jurisdiction over Novitium because it is a limited liability company organized and existing under the laws of Delaware. Novitium is registered to do business as a domestic company in Delaware (File Number 5947222).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 63, and therefore denies them.

64. Additionally, this Court has personal jurisdiction over Novitium because, on information and belief, Novitium, inter alia, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself

of the privilege of doing business in the State of Delaware; and intends to sell the Novitium ANDA Products in the State of Delaware upon approval of the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 64, and therefore denies them.

65. On information and belief, Novitium is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Novitium manufactures, distributes, markets and/or sells throughout the United States and in Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 65, and therefore denies them.

66. On information and belief, Novitium is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 66, and therefore denies them.

67. Novitium has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated October 12, 2023, sent by Novitium Pharma LLC to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("Novitium's Notice Letter"), Novitium prepared and filed the Novitium ANDA with the intention of seeking to market the Novitium ANDA Products nationwide, including within Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 67, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 68, and therefore denies them.

69. On information and belief, Novitium knows and intends that the Novitium ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. Novitium intends to take advantage of its established channels of distribution in Delaware for the sale of the Novitium ANDA Products.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 69, and therefore denies them.

70. Novitium has engaged in patent litigation concerning FDA-approved drug products in Delaware and has not contested personal jurisdiction or venue in Delaware in such litigation. *See, e.g.*, *Azurity Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 21-1286, D.I. 137 (D. Del. Feb. 24, 2022); *iCeutica Pty Ltd. v. Novitium Pharma LLC*, C.A. No. 18-599, D.I. 8 (D. Del. May 14, 2018).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 70, and therefore denies them.

71. Venue is proper in this district for Novitium Pharma LLC pursuant to 28 U.S.C. § 1400(b) because, inter alia, it is a limited liability company organized and existing under the laws of the State of Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 71, and therefore denies them.

Zenara

72. This Court has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because, on information and belief, each, inter alia, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell the Zenara ANDA Products in the State of Delaware upon approval of the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 72, and therefore denies them.

73. On information and belief, Zenara is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products,

either directly or through subsidiaries, agents, and/or alter egos, throughout the United States, including in Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 73, and therefore denies them.

74. On information and belief, Zenara is licensed to sell pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 74, and therefore denies them.

75. Zenara has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated October 12, 2023, sent by Zenara Pharma Private Limited to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B) ("Zenara's Notice Letter"), Zenara prepared and filed the Zenara ANDA with the intention of seeking to market the Zenara ANDA Products nationwide, including within Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 75, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 76, and therefore denies them.

77. On information and belief, Zenara knows and intends that the Zenara ANDA Products will be distributed and sold in the State of Delaware and will thereby displace sales of WAKIX®, causing injury to Plaintiffs. Zenara intends to take advantage of its established channels of distribution in Delaware for the sale of the Zenara ANDA Products.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 77, and therefore denies them.

78. Zenara Pharma Private Limited has engaged in patent litigation concerning FDA-approved drug products in Delaware and has not contested personal jurisdiction or venue in

Delaware in such litigation. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Zenara Pharma Priv. Ltd.*, C.A. No. 22-379 (GBW), D.I. 13 (D. Del. Apr. 5, 2022); *Newron Pharms. S.p.A. v. Aurobindo Pharma Ltd.*, C.A. No. 21-843 (RGA), D.I. 17 (D. Del. July 13, 2021); *Otsuka Pharm. Co., Ltd. v. Zenara Pharma Priv. Ltd.*, No. 19-1938 (LPS), D.I. 8 (D. Del. Oct. 30, 2019); *Genzyme Corp. v. Zenara Pharma Priv. Ltd.*, No. 19-264 (CFC), D.I. 7 (D. Del. Feb. 27, 2019).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 78, and therefore denies them.

79. Alternatively, this Court has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) each is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) each has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Zenara ANDA, and/or manufacturing and/or selling pharmaceutical products throughout the United States including in Delaware, such that this Court's exercise of jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited satisfies due process.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 79, and therefore denies them.

80. Venue is proper in this district for Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, inter alia, each is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district, and is subject to personal jurisdiction in Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 80, and therefore denies them.

AET'S ANDA NO. 218892

81. AET has submitted ANDA No. 218892 to FDA, or caused ANDA No. 218892 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 pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the '947 and '197 patents.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 81, and therefore denies them.

82. AET sent a letter to Harmony and Bioprojet, dated October 14, 2023, identified as "Pitolisant tablets, 4.45 mg and 17.8 mg, ANDA No. 218892, Notice of Paragraph IV Certification for U.S. Patent Nos. 8,207,197 and 8,486,947." AET's Notice Letter represented that AET had

submitted to FDA the AET ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the AET ANDA before the expiration of the '947 and '197 patents listed in the Orange Book for WAKIX®. Thus, AET's purpose in submitting the AET ANDA is to manufacture and market the AET ANDA Products before the expiration of the '947 and '197 patents.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 82, and therefore denies them.

83. According to applicable regulations, Notice Letters such as AET's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 83, and therefore denies them.

84. AET's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("AET's Detailed Statement").

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 84, and therefore denies them.

85. AET's Detailed Statement does not dispute infringement of Claims 1–5 or 10–14 of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 85, and therefore denies them.

86. AET's Detailed Statement does not dispute infringement of any of the claims of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 86, and therefore denies them.

87. AET's Notice Letter contained a purported offer of confidential access ("the AET Offer") that contained unreasonable restrictions regarding access to AET's ANDA. For example, the AET Offer did not permit any in-house attorneys to access AET's ANDA. Nor did it permit any scientific experts or consultants to access AET's ANDA. Additionally, the AET Offer

contained provisions that unreasonably restricted the ability of outside counsel receiving access to AET's ANDA. The restrictions the AET Offer placed on access to AET's ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 87, and therefore denies them.

88. Outside counsel for Plaintiffs negotiated in good faith with counsel for AET but were unable to reach agreement on reasonable terms of confidential access to the ANDA. In correspondence dated October 25, 2023, counsel for Plaintiffs proposed edits to the AET Offer based on reasonable confidentiality terms. Over two weeks later, on November 13, 2023, counsel for AET proposed additional changes to the AET Offer, which similarly contained unreasonable restrictions on access to AET's ANDA. Plaintiffs' counsel provided additional edits to the AET Offer on November 17, 2023, to which AET has not responded. To date, Plaintiffs have not received access to AET's ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 88, and therefore denies them.

89. On information and belief, AET was responsible for the submission of the AET ANDA, participated in the preparation and submission of the AET ANDA, and intends to support the further prosecution of the AET ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 89, and therefore denies them.

90. If FDA approves the AET ANDA, AET will manufacture, offer for sale, or sell the AET ANDA Products within the United States, including within Delaware, or will import the AET ANDA Products into the United States, including Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 90, and therefore denies them.

91. If FDA approves the AET ANDA, the manufacture, use, offer for sale, sale, or importation of the AET ANDA Products will directly infringe the '947 and '197 patents, and AET

will actively induce or contribute to the manufacture, use, offer for sale, or sale of the AET ANDA Products within the United States, including within Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 91, and therefore denies them.

92. With the submission of the AET ANDA, AET seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the AET ANDA Products before the expiration of such patent (here, the '947 and '197 patents). Thus, AET has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If AET engages in the commercial manufacture, use, offer to sell, sale, or importation of the AET ANDA Products prior to the expiration of the '947 and '197 patents, it will infringe, contribute to the infringement of, and/or induce the infringement of the '947 and '197 patents under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 92, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 93, and therefore denies them.

ANNORA'S ANDA NO. 218832

94. Annora has submitted ANDA No. 218832 to FDA, or caused ANDA No. 218832 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 pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the patents-in-suit.

ANSWER: Defendant Annora admits that Annora caused the submission of ANDA No. 218832 to the FDA seeking approval for the manufacture, use or sale of the Proposed ANDA products, prior to the expiration of the patents-in-suit. Defendant Annora denies any remaining allegations in Paragraph 94.

95. Annora sent a letter to Harmony and Bioprojet, dated October 16, 2023, identified as "Notice of Certification under 21 U.S.C. § 355(j)(2)(B)(ii)(§ 505(j)(2)(B)(ii) [sic] of the Federal Food, Drug, and Cosmetic Act) and 21 C.F.R. § 314.95." Annora's Notice Letter represented that

Annora had submitted to FDA the Annora ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Annora ANDA before the expiration of the '947, '197, and '430 patents listed in the Orange Book for WAKIX®. Thus, Annora's purpose in submitting the Annora ANDA is to manufacture and market the Annora ANDA Products before the expiration of the patents-in-suit.

ANSWER: Defendant Annora admits that Annora caused a letter to be sent to Plaintiffs on or about October 16, 2023 regarding the submission of ANDA No. 218832 to notify Plaintiffs that they had submitted a Paragraph IV certification under 35 U.S.C. § 355(j)(2)(B)(ii) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product. Defendant Annora denies any remaining allegations in Paragraph 95.

96. Annora's Notice Letter stated that the Paragraph IV certification in the Annora ANDA alleges that the '947, '197, and '430 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Annora ANDA Products.

ANSWER: Defendant Annora admits that Annora's Notice Letter stated that the Paragraph IV certification submitted with ANDA 218832 alleges that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Annora ANDA products.

97. According to applicable regulations, Notice Letters such as Annora's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Paragraph 97 contains legal conclusions to which no response is required.

98. Annora's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Annora's Detailed Statement").

ANSWER: Defendant Annora admits that Annora's Notice Letter contained a detailed statement of the factual and legal basis for its Paragraph IV certification.

99. Annora's Detailed Statement does not dispute infringement of Claims 1–14 or 16–17 of the '947 patent.

ANSWER: Denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement).

100. Annora's Detailed Statement does not dispute infringement of Claims 1–2 or 10 of the '197 patent.

ANSWER: Denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement)

101. Annora's Detailed Statement does not dispute infringement of Claims 3–4 of the '430 patent.

ANSWER: Denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement)

102. Annora's Notice Letter contained a purported offer of confidential access ("the Annora Offer") that contained unreasonable restrictions regarding access to Annora's ANDA. For example, the Annora Offer did not permit any in-house attorneys, nor scientific experts, access to Annora's ANDA. Additionally, the Annora Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to Annora's ANDA. The restrictions the Annora Offer placed on access to Annora's ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Paragraph 102 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that Annora's Notice Letter included an offer of confidential access. Defendant Annora denies any remaining allegations in Paragraph 102.

103. Outside counsel for Plaintiffs negotiated in good faith with Annora but were unable to reach agreement on reasonable terms of confidential access to the ANDA. In correspondence dated November 2, 2023, counsel for Plaintiffs proposed edits to Annora's Offer consistent with protective orders in similar matters. *See, e.g.*, *Pierre Fabre Dermatologie v. Annora Pharma Priv., Ltd.*, C.A. No. 22-1442, D.I. 27 (D. Del. Feb. 9, 2023); *UCB, Inc. v. Annora Pharma Priv. Ltd.*, C.A. No. 20-987, D.I. 83 (D. Del. Mar. 29, 2021). Annora has not responded to that

counterproposal, despite subsequent emails from Plaintiffs' counsel on November 8, 2023, and November 15, 2023. To date, Plaintiffs have not received access to Annora's ANDA.

ANSWER: Paragraph 103 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that the parties attempted to negotiate reasonable terms of confidential access to the ANDA. Defendant Annora admits that no agreement was reached as of the filing of the Complaint. Defendant Annora denies any remaining allegations in Paragraph 103.

104. On information and belief, Annora was responsible for the submission of the Annora ANDA, has participated in the preparation and submission of the Annora ANDA, has provided material support to the preparation and submission of the Annora ANDA, and intends to support the further prosecution of the Annora ANDA.

ANSWER: Defendant Annora admits that Annora caused the submission of ANDA No. 218832 to the FDA seeking approval for the Proposed ANDA Product. Defendant Annora denies any remaining allegations in Paragraph 104.

105. If FDA approves the Annora ANDA, Annora will manufacture, offer for sale, or sell the Annora ANDA Products within the United States, including within Delaware, or will import the Annora ANDA Products into the United States, including Delaware.

ANSWER: Defendant Annora does not contest personal jurisdiction for the purposes of this action only and denies any remaining allegations in Paragraph 105.

106. If FDA approves the Annora ANDA, the manufacture, use, offer for sale, sale, or importation of the Annora ANDA Products will directly infringe the patents-in-suit, and Annora will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Annora ANDA Products within the United States, including within Delaware.

ANSWER: Denied.

107. With the submission of the Annora ANDA, Annora seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Annora ANDA Products before the expiration of such patent (here, all of the patents-in-suit). Thus, Annora has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If Annora engages in the commercial manufacture, use, offer to sell, sale, or importation of the Annora ANDA Products prior to the expiration of the

patents-in-suit, it will infringe, contribute to the infringement of, and/or induce the infringement of the claims in the patents-in-suit under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 107 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that Annora's ANDA No. 218832 seeks approval to engage in the commercial manufacture, use, or sale of the Proposed ANDA Product, and denies the remaining allegations in Paragraph 107.

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

ANSWER: Paragraph 108 contains legal conclusions to which no response is required. To the extent a response is required, Defendant Annora admits that this action was filed within forty-five days of receipt of Annora's Notice Letter.

NOVITIUM'S ANDA NO. 218495

109. Novitium has submitted ANDA No. 218495 to FDA, or caused ANDA No. 218495 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 pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the patents-in-suit.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 109, and therefore denies them.

110. Novitium sent a letter to Harmony and Bioprojet, dated October 12, 2023, identified as "Pitolisant Tablets 4.45 mg and 17.8 mg, United States Patent Nos. 8,207,197; 8,354,430; and 8,486,947, Notice of Paragraph IV Certification." Novitium's Notice Letter represented that Novitium had submitted to FDA the Novitium ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Novitium ANDA before the expiration of the '947, '197, and '430 patents listed in the Orange Book for WAKIX®. Thus, Novitium's purpose in submitting the Novitium ANDA is to manufacture and market the Novitium ANDA Products before the expiration of the patents-in-suit.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 110, and therefore denies them.

111. Novitium's Notice Letter stated that the Paragraph IV certification in the Novitium ANDA alleges that the '947, '197, and '430 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Novitium ANDA Products.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 111, and therefore denies them.

112. According to applicable regulations, Notice Letters such as Novitium's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." See 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 112, and therefore denies them.

113. Novitium's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Novitium's Detailed Statement").

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 113, and therefore denies them.

114. Novitium's Detailed Statement does not dispute infringement of any claim of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 114, and therefore denies them.

115. Novitium's Detailed Statement does not assert that any claim of the '197 patent is invalid.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 115, and therefore denies them.

116. Novitium's Detailed Statement does not assert that any claim of the '430 patent is invalid.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 116, and therefore denies them.

117. Novitium's Notice Letter contained a purported offer of confidential access ("the Novitium Offer") that contained unreasonable restrictions regarding access to Novitium's ANDA. For example, the Novitium Offer did not permit any in-house attorneys, nor scientific experts, access to Novitium's ANDA. Additionally, the Novitium Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to Novitium's ANDA. The restrictions the Novitium Offer placed on access to Novitium's ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 117, and therefore denies them.

118. Outside counsel for Plaintiffs negotiated in good faith with counsel for Novitium but were unable to reach agreement on reasonable terms of confidential access to the ANDA. In correspondence dated November 2, 2023, counsel for Plaintiffs proposed edits to the Novitium Offer consistent with protective orders in similar matters. See, e.g., iCeutica Pty. Ltd. v. Novitium Pharma LLC, C.A. No. 18-599, D.I. 23 (D. Del. Aug. 30, 2018). Between November 2, 2023 and November 13, 2023, the parties exchanged correspondence regarding the terms of access to the Novitium ANDA. Counsel for Novitium continued to insist on unreasonable restrictions, inconsistent with the provisions of protective orders Novitium has agreed to in past litigation. On November 13, 2023, Plaintiffs' counsel requested Novitium's counsel meet and confer to discuss reasonable terms. Novitium's counsel responded on November 21, 2023, without agreeing to a meet and confer, and continued to insist on unreasonable terms, such as denying ANDA access to any scientific experts. To date, Plaintiffs have not received access to Novitium's ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 118, and therefore denies them.

119. On information and belief, Novitium was responsible for the submission of the Novitium ANDA, has participated in the preparation and submission of the Novitium ANDA, has provided material support to the preparation and submission of the Novitium ANDA, and intends to support the further prosecution of the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 119, and therefore denies them.

120. If FDA approves the Novitium ANDA, Novitium will manufacture, offer for sale, or sell the Novitium ANDA Products within the United States, including within Delaware, or will import the Novitium ANDA Products into the United States, including Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 120, and therefore denies them.

121. If FDA approves the Novitium ANDA, the manufacture, use, offer for sale, sale, or importation of the Novitium ANDA Products will directly infringe the patents-in-suit, and Novitium will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Novitium ANDA Products within the United States, including within Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 121, and therefore denies them.

122. With the submission of the Novitium ANDA, Novitium seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Novitium ANDA Products before expiry of such patent (here, all of the patents-in-suit). Thus, Novitium has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If Novitium engages in the commercial manufacture, use, offer to sell, sale, or importation of the Novitium ANDA Products prior to the expiration of the patents-in-suit, it will infringe, contribute to the infringement of and/or induce the infringement of the claims in the patents-in-suit under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 122, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 123, and therefore denies them.

ZENARA'S ANDA NO. 218796

124. Zenara has submitted ANDA No. 218796 to FDA, or caused ANDA No. 218796 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 pitolisant hydrochloride tablets as a purported generic version of WAKIX® prior to the expiration of the patents-in-suit.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 124, and therefore denies them.

125. Zenara sent a letter to Harmony and Bioprojet, dated October 12, 2023, identified as "Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos.: 8,207,197; 8,354,430; and 8,486,947 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act: Pitolisant Tablets, 4.45 mg and 17.8 mg." Zenara's Notice Letter represented that Zenara had submitted to FDA the Zenara ANDA and a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Zenara ANDA before the expiration of the '947, '197, and '430 patents listed in the Orange Book for WAKIX®. Thus, Zenara's purpose in submitting the Zenara ANDA is to manufacture and market the Zenara ANDA Products before the expiration of the patents-in-suit.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 125, and therefore denies them.

126. Zenara's Notice Letter stated that the Paragraph IV certification in the Zenara ANDA alleges that the '947, '197, and '430 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Zenara ANDA Products.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 126, and therefore denies them.

127. According to applicable regulations, Notice Letters such as Zenara's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." See 21 C.F.R. § 314.95(c)(7); see also 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 127, and therefore denies them.

128. Zenara's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Zenara's Detailed Statement").

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 128, and therefore denies them.

129. Zenara's Detailed Statement does not assert that any claim of the '197 patent is invalid.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 129, and therefore denies them.

130. Zenara's Detailed Statement does not assert that any claim of the '430 patent is invalid.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 130, and therefore denies them.

131. Zenara's Notice Letter contained a purported offer of confidential access ("the Zenara Offer") that contained unreasonable restrictions regarding access to Zenara's ANDA. The Zenara Offer did not permit in-house attorneys, nor scientific experts, access to Zenara's ANDA. Additionally, the Zenara Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to Zenara's ANDA. The restrictions the Zenara Offer placed on access to Zenara's ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 131, and therefore denies them.

132. Outside counsel for Plaintiffs negotiated in good faith with counsel for Zenara but were unable to reach agreement on reasonable terms of confidential access to the ANDA. In correspondence dated November 2, 2023, counsel for Plaintiffs proposed edits to the Zenara Offer consistent with protective orders in similar matters. See, e.g., Otsuka Pharma. Co., Ltd. v. Zenara Pharma Priv. Ltd., C.A. No. 19-1932, D.I. 38 (D. Del. Nov. 13, 2020); AbbVie Inc. v. Alkem Labs. Ltd., C.A. No. 22-1423, D.I. 100 (D. Del. May 11, 2023). On November 8, 2023, Zenara's counsel rejected Plaintiffs' counterproposal with no explanation. On November 9, 2023, Plaintiffs' counsel

requested to meet and confer, and on that same day Zenara's counsel said it would refuse to do so. To date, Plaintiffs have not received access to Zenara's ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 132, and therefore denies them.

133. On information and belief, Zenara was responsible for the submission of the Zenara ANDA, has participated in the preparation and submission of the Zenara ANDA, has provided material support to the preparation and submission of the Zenara ANDA, and intends to support the further prosecution of the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 133, and therefore denies them.

134. If FDA approves the Zenara ANDA, Zenara will manufacture, offer for sale, or sell the Zenara ANDA Products within the United States, including within Delaware, or will import the Zenara ANDA Products into the United States, including Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 134, and therefore denies them.

135. If FDA approves the Zenara ANDA, the manufacture, use, offer for sale, sale, or importation of the Zenara ANDA Products will directly infringe the patents-in-suit, and Zenara will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Zenara ANDA Products within the United States, including within Delaware.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 135, and therefore denies them.

136. With the submission of the Zenara ANDA, Zenara seeks approval of a drug claimed in a patent or the use of which is claimed in a patent with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Zenara ANDA Products before expiry of such patent (here, all of the patents-in-suit). Thus, Zenara has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). If Zenara engages in the commercial manufacture, use, offer to sell, sale, or importation of the Zenara ANDA Products prior to the expiration of the patents-in-suit, it will infringe, contribute to the infringement of and/or induce infringement of the claims of the patents-in-suit under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 136, and therefore denies them.

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

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 137, and therefore denies them.

COUNT I
INFRINGEMENT OF THE '947 PATENT BY AET

138. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

139. On information and belief, AET has submitted or caused the submission of the AET ANDA to FDA and continues to seek FDA approval of the AET ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 139, and therefore denies them.

140. Plaintiffs own all rights, title, and interest in and to the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 140, and therefore denies them.

141. AET did not dispute infringement of Claims 1–5 and 10–14 of the '947 patent in its Notice Letter. If AET had a factual or legal basis to contest infringement of Claims 1–5 or 10–14 of the '947 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 141, and therefore denies them.

142. AET has infringed at least Claims 1–5 and 10–14 of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 142, and therefore denies them.

143. According to AET's Notice Letter, the AET ANDA Products contain pitolisant hydrochloride.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 143, and therefore denies them.

144. AET has infringed the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the AET ANDA and seeking FDA approval of the AET ANDA prior to the expiration of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 144, and therefore denies them.

145. On information and belief, the importation, manufacture, sale, offer for sale, or use of the AET ANDA Products prior to the expiration of the '947 patent would infringe the '947 patent under 35 U.S.C. § 271(a), and/or AET would induce the infringement of and/or contribute to the infringement of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 145, and therefore denies them.

146. The importation, manufacture, sale, offer for sale, or use of the AET ANDA Products in the United States, including in the State of Delaware, would directly infringe the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 146, and therefore denies them.

147. Upon FDA approval of the AET ANDA, AET will market and distribute the AET ANDA Products to resellers, pharmacies, health care professionals, and end users of the AET ANDA Products. Accompanying the AET ANDA Products, AET will also knowingly and intentionally include a product label and insert containing instructions for administering the AET ANDA Products. Accordingly, AET will induce physicians and other health care professionals, resellers, pharmacies, and end users of the AET ANDA Products to directly infringe the '947 patent. In addition, on information and belief, AET will encourage acts of direct infringement with

knowledge of the '947 patent and knowledge that it is encouraging infringement. AET's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 147, and therefore denies them.

148. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218892, AET will make, use, offer to sell, or sell the AET ANDA Products within the United States, or will import the AET ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 148, and therefore denies them.

149. AET had actual knowledge of the '947 patent prior to submitting the AET ANDA, was aware that the submission of the AET ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent, and was aware that use of the AET ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 149, and therefore denies them.

150. AET submitted the AET ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the AET ANDA Products. AET did not dispute infringement of Claims 1–5 or 10–14 of the '947 patent. AET's conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 150, and therefore denies them.

151. Plaintiffs will be irreparably harmed if AET is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and AET, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 151, and therefore denies them.

COUNT II
INFRINGEMENT OF THE '197 PATENT BY AET

152. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

153. On information and belief, AET has submitted or caused the submission of the AET ANDA to FDA and continues to seek FDA approval of the AET ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 153, and therefore denies them.

154. Plaintiffs own all rights, title, and interest in and to the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 154, and therefore denies them.

155. AET did not dispute infringement of any claim of the '197 patent in its Notice Letter. If AET had a factual or legal basis to contest infringement of any claim of the '197 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 155, and therefore denies them.

156. AET has infringed all claims of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 156, and therefore denies them.

157. AET has infringed the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the AET ANDA and seeking FDA approval of the AET ANDA prior to the expiration of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 157, and therefore denies them.

158. On information and belief, the importation, manufacture, sale, offer for sale, or use of the AET ANDA Products prior to the expiration of the '197 patent would infringe the '197 patent under 35 U.S.C. § 271(a), and/or AET would induce the infringement of and/or contribute to the infringement of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 158, and therefore denies them.

159. On information and belief, if the AET ANDA is approved, AET and its affiliates will make, offer for sale, sell, or otherwise distribute the AET ANDA Products in the United States, including in the State of Delaware, directly infringing the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 159, and therefore denies them.

160. On information and belief, upon FDA approval of the AET ANDA, AET will market and distribute the AET ANDA Products to resellers, pharmacies, health care professionals, and end users of the AET ANDA Products. Accompanying the AET ANDA Products, AET will also knowingly and intentionally include a product label and insert containing instructions for administering the AET ANDA Products. Accordingly, AET will induce physicians and other health care professionals, resellers, pharmacies, and end users of the AET ANDA Products to directly infringe the '197 patent. In addition, on information and belief, AET will encourage acts of direct infringement with knowledge of the '197 patent and knowledge that it is encouraging infringement. AET's conduct would intentionally actively induce and/or contribute to the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 160, and therefore denies them.

161. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218892, AET will make, use, offer to sell, or sell the AET ANDA Products within the United States, or will import the AET ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 161, and therefore denies them.

162. AET had actual knowledge of the '197 patent prior to submitting the AET ANDA and was aware that the submission of the AET ANDA with the request for FDA approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 162, and therefore denies them.

163. AET submitted the AET ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the AET ANDA Products. AET did not dispute infringement of any claim of the '197 patent. AET's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 163, and therefore denies them.

164. Plaintiffs will be irreparably harmed if AET is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and AET, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 164, and therefore denies them.

COUNT III
INFRINGEMENT OF THE '947 PATENT BY ANNORA

165. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

166. On information and belief, Annora has submitted or caused the submission of the Annora ANDA to FDA and continues to seek FDA approval of the Annora ANDA.

ANSWER: Defendant Annora admits that Annora submitted ANDA No. 218832 to the FDA seeking approval for the Proposed ANDA Product. Defendant Annora denies any remaining allegations in Paragraph 166.

167. Plaintiffs own all rights, title, and interest in and to the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 167, and therefore denies them.

168. Annora did not dispute infringement of Claims 1–14 or 16–17 of the '947 patent in its Notice Letter. If Annora had a factual or legal basis to contest infringement of Claims 1–14 and 16–17 of the '947 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Paragraph 168 contains legal conclusions to which no response is required. To the extent a response is required, denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement).

169. Annora has infringed at least Claims 1–5 and 10–14 of the '947 patent.

ANSWER: Denied.

170. According to Annora's Notice Letter, the Annora ANDA Products contain pitolisant hydrochloride.

ANSWER: Admitted.

171. Annora has infringed the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Annora ANDA and seeking FDA approval of the Annora ANDA prior to the expiration of the '947 patent.

ANSWER: Denied.

172. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Annora ANDA Products prior to the expiration of the '947 patent would infringe the '947 patent under 35 U.S.C. § 271(a), and/or Annora would induce the infringement of and/or contribute to the infringement of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

173. The importation, manufacture, sale, offer for sale, or use of the Annora ANDA Products in the United States, including in the State of Delaware, would directly infringe the '947 patent.

ANSWER: Denied.

174. Upon FDA approval of the Annora ANDA, Annora will market and distribute the Annora ANDA Products to resellers, pharmacies, health care professionals, and end users of the

Annora ANDA Products. Accompanying the Annora ANDA Products, Annora will also knowingly and intentionally include a product label and insert containing instructions for administering the Annora ANDA Products. Accordingly, Annora will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Annora ANDA Products to directly infringe the '947 patent. In addition, on information and belief, Annora will encourage acts of direct infringement with knowledge of the '947 patent and knowledge that it is encouraging infringement. Annora's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

ANSWER: Denied.

175. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218832, Annora will make, use, offer to sell, or sell the Annora ANDA Products within the United States, or will import the Annora ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '947 patent.

ANSWER: Denied.

176. Annora had actual knowledge of the '947 patent prior to submitting the Annora ANDA, was aware that the submission of the Annora ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent, and was aware that use of the Annora ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

ANSWER: Defendant Annora admits that Annora's Notice Letter stated, *inter alia*, that "the FDA has received an Abbreviated New Drug Application ("ANDA") for Pitolisant Hydrochloride Tablets; Oral, Eq. 4.45mg Base and 17.8mg Base … The ANDA … contains a … Paragraph IV certification … to obtain approval to engage in the commercial manufacture, use or sale of Annora's Pitolisant Product, before the expiration of the challenged patents." Defendant Annora further admits that the '947 patent is listed as a challenged patent in Annora's Notice Letter. Defendant Annora denies any remaining allegations in Paragraph 176.

177. Annora submitted the Annora ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Annora ANDA Products. Annora did not dispute infringement of Claims 1–5 and 10–14 of the '947 patent. Annora's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Denied.

178. Plaintiffs will be irreparably harmed if Annora is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Annora, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT IV
INFRINGEMENT OF THE '197 PATENT BY ANNORA

179. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

180. On information and belief, Annora has submitted or caused the submission of the Annora ANDA to FDA and continues to seek FDA approval of the Annora ANDA.

ANSWER: Defendant Annora admits that Annora submitted ANDA No. 218832 to the FDA seeking approval for the Proposed ANDA Product. Defendant Annora denies any remaining allegations in Paragraph 180.

181. Plaintiffs own all rights, title, and interest in and to the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 181, and therefore denies them.

182. Annora did not dispute infringement of Claims 1–2 or 10 of the '197 patent in its Notice Letter. If Annora had a factual or legal basis to contest infringement of any claim of the '197 patent, it was required by applicable regulations to state such a basis in its Notice Letter. See 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Paragraph 182 contains legal conclusions to which no response is required. To the extent a response is required, denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement).

183. Annora has infringed at least Claims 1–2 and 10 of the '197 patent.

ANSWER: Denied.

184. Annora has infringed the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Annora ANDA and seeking FDA approval of the Annora ANDA prior to the expiration of the '197 patent.

ANSWER: Denied.

185. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Annora ANDA Products prior to the expiration of the '197 patent would infringe the '197 patent under 35 U.S.C. § 271(a), and/or Annora would induce the infringement of and/or contribute to the infringement of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

186. On information and belief, if the Annora ANDA is approved, Annora and its affiliates will make, offer for sale, sell, or otherwise distribute the Annora ANDA Products in the United States, including in the State of Delaware, directly infringing the '197 patent.

ANSWER: Denied.

187. On information and belief, upon FDA approval of the Annora ANDA, Annora will market and distribute the Annora ANDA Products to resellers, pharmacies, health care professionals, and end users of the Annora ANDA Products. Accompanying the Annora ANDA Products, Annora will also knowingly and intentionally include a product label and insert containing instructions for administering the Annora ANDA Products. Accordingly, Annora will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Annora ANDA Products to directly infringe the '197 patent. In addition, on information and belief, Annora will encourage acts of direct infringement with knowledge of the '197 patent and knowledge that it is encouraging infringement. Annora's conduct would intentionally actively induce and/or contribute to the infringement of the '197 patent.

ANSWER: Denied.

188. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218832, Annora will make, use, offer to sell, or sell the Annora ANDA Products within the United States, or will import the Annora ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '197 patent.

ANSWER: Denied.

189. Annora had actual knowledge of the '197 patent prior to submitting the Annora ANDA and was aware that the submission of the Annora ANDA with the request for FDA approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

ANSWER: Paragraph 189 contains a legal conclusion to which no response is required. To the extent a response is required, Defendant Annora admits that Annora's Notice Letter stated, *inter alia*, that "the FDA has received an Abbreviated New Drug Application ("ANDA") for Pitolisant Hydrochloride Tablets; Oral, Eq. 4.45mg Base and 17.8mg Base … The ANDA … contains a … Paragraph IV certification … to obtain approval to engage in the commercial manufacture, use or sale of Annora's Pitolisant Product, before the expiration of the challenged patents." Defendant Annora further admits that the '197 patent is listed as a challenged patent in Annora's Notice Letter. Defendant Annora denies any remaining allegations in Paragraph 189.

190. Annora submitted the Annora ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Annora ANDA Products. Annora did not dispute infringement of Claims 1–2 or 10 of the '197 patent. Annora's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Denied.

191. Plaintiffs will be irreparably harmed if Annora is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Annora, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT V
INFRINGEMENT OF THE '430 PATENT BY ANNORA

192. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

193. On information and belief, Annora has submitted or caused the submission of the Annora ANDA to FDA and continues to seek FDA approval of the Annora ANDA.

ANSWER: Defendant Annora admits that Annora submitted ANDA No. 218832 to the FDA seeking approval for the Proposed ANDA Product. Defendant Annora denies any remaining allegations in Paragraph 193.

194. Plaintiffs own all rights, title, and interest in and to the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 194, and therefore denies them.

195. Annora did not dispute infringement of Claims 3–4 of the '430 patent in its Notice Letter. If Annora had a factual or legal basis to contest infringement of Claims 3 or 4 of the '430 patent, it was required by applicable regulations to state such a basis in its Notice Letter. See 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Paragraph 195 contains legal conclusions to which no response is required. To the extent a response is required, denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (cited in Annora's Detailed Statement).

196. Annora has infringed at least Claims 3–4 of the '430 patent.

ANSWER: Denied.

197. Annora has infringed the '430 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Annora ANDA and seeking FDA approval of the Annora ANDA prior to the expiration of the '430 patent.

ANSWER: Denied.

198. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Annora ANDA Products prior to the expiration of the '430 patent would infringe the '430 patent under 35 U.S.C. § 271(a), and/or Annora would induce the infringement of and/or contribute to the infringement of the '430 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

199. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Annora ANDA Products in the United States, including in the State of Delaware, would directly infringe the '430 patent.

ANSWER: Denied.

200. On information and belief, upon FDA approval of the Annora ANDA, Annora will market and distribute the Annora ANDA Products to resellers, pharmacies, health care professionals, and end users of the Annora ANDA Products. Accompanying the Annora ANDA Products, Annora will also knowingly and intentionally include a product label and insert containing instructions for administering the Annora ANDA Products. Accordingly, Annora will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Annora ANDA Products to directly infringe the '430 patent. In addition, on information and belief, Annora will encourage acts of direct infringement with knowledge of the '430 patent and knowledge that it is encouraging infringement. Annora's conduct would intentionally actively induce and/or contribute to the infringement of the '430 patent.

ANSWER: Denied.

201. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218832, Annora will make, use, offer to sell, or sell the Annora ANDA Products within the United States, or will import the Annora ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '430 patent.

ANSWER: Denied.

202. Annora had actual knowledge of the '430 patent prior to submitting the Annora ANDA, was aware that the submission of the Annora ANDA with the request for FDA approval prior to the expiration of the '430 patent would constitute an act of infringement of the '430 patent, and was aware that use of the Annora ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '430 patent.

ANSWER: Paragraph 202 contains a legal conclusion to which no response is required. To the extent a response is required, Defendant Annora admits that Annora's Notice Letter stated, *inter alia*, that "the FDA has received an Abbreviated New Drug Application ("ANDA") for Pitolisant Hydrochloride Tablets; Oral, Eq. 4.45mg Base and 17.8mg Base … The ANDA … contains a … Paragraph IV certification … to obtain approval to engage in the commercial manufacture, use or sale of Annora's Pitolisant Product, before the expiration of the challenged patents." Defendant Annora further admits that the '430 patent is listed as a challenged patent in Annora's Notice Letter. Defendant Annora denies any remaining allegations in Paragraph 202.

203. Annora submitted the Annora ANDA without a reasonable basis for asserting the '430 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Annora ANDA Products. Annora did not dispute infringement of Claims 3–4 of the '430 patent. Annora's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '430 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Denied.

204. Plaintiffs will be irreparably harmed if Annora is not enjoined from infringing the '430 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Annora, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT VI
INFRINGEMENT OF THE '947 PATENT BY NOVITIUM

205. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

206. On information and belief, Novitium has submitted or caused the submission of the Novitium ANDA to FDA and continues to seek FDA approval of the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 206, and therefore denies them.

207. Plaintiffs own all rights, title, and interest in and to the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 207, and therefore denies them.

208. Novitium did not dispute infringement of any claim of the '947 patent in its Notice Letter. If Novitium had a factual or legal basis to contest infringement of any claim of the '947

patent, it was required by applicable regulations to state such a basis in its Notice Letter. See 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 208, and therefore denies them.

209. Novitium has infringed at least Claims 1–5 and 10–14 of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 209, and therefore denies them.

210. According to Novitium's Notice Letter, the Novitium ANDA Products contain pitolisant hydrochloride.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 210, and therefore denies them.

211. Novitium has infringed the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Novitium ANDA and seeking FDA approval of the Novitium ANDA prior to the expiration of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 211, and therefore denies them.

212. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novitium ANDA Products prior to the expiration of the '947 patent would infringe the '947 patent under 35 U.S.C. § 271(a), and/or Novitium would induce the infringement of and/or contribute to the infringement of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 212, and therefore denies them.

213. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novitium ANDA Products in the United States, including in the State of Delaware, would directly infringe the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 213, and therefore denies them.

214. On information and belief, upon FDA approval of the Novitium ANDA, Novitium will market and distribute the Novitium ANDA Products to resellers, pharmacies, health care

professionals, and end users of the Novitium ANDA Products. Accompanying the Novitium ANDA Products, Novitium will also knowingly and intentionally include a product label and insert containing instructions for administering the Novitium ANDA Products. Accordingly, Novitium will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Novitium ANDA Products to directly infringe the '947 patent. In addition, on information and belief, Novitium will encourage acts of direct infringement with knowledge of the '947 patent and knowledge that it is encouraging infringement. Novitium's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 214, and therefore denies them.

215. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218495, Novitium will make, use, offer to sell, or sell the Novitium ANDA Products within the United States, or will import the Novitium ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 215, and therefore denies them.

216. Novitium had actual knowledge of the '947 patent prior to submitting the Novitium ANDA, was aware that the submission of the Novitium ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent, and was aware that use of the Novitium ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 216, and therefore denies them.

217. Novitium submitted the Novitium ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Novitium ANDA Products. Novitium did not dispute infringement of any claims of the '947 patent. Novitium's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 217, and therefore denies them.

218. Plaintiffs will be irreparably harmed if Novitium is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of

hardships between Plaintiffs and Novitium, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 218, and therefore denies them.

COUNT VII
INFRINGEMENT OF THE '197 PATENT BY NOVITIUM

219. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

220. On information and belief, Novitium has submitted or caused the submission of the Novitium ANDA to FDA and continues to seek FDA approval of the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 220, and therefore denies them.

221. Plaintiffs own all rights, title, and interest in and to the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 221, and therefore denies them.

222. On information and belief, Novitium has infringed one or more claims of the '197 patent, including at least Claim 1 of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 222, and therefore denies them.

223. On information and belief, Novitium has infringed the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Novitium ANDA and seeking FDA approval of the Novitium ANDA prior to the expiration of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 223, and therefore denies them.

224. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novitium ANDA Products prior to the expiration of the '197 patent would infringe the '197 patent under 35 U.S.C. § 271(a), and/or Novitium would induce the infringement of and/or contribute to the infringement of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 224, and therefore denies them.

225. On information and belief, if the Novitium ANDA is approved, Novitium and its affiliates will make, offer for sale, sell, or otherwise distribute the Novitium ANDA Products in the United States, including in the State of Delaware, directly infringing the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 225, and therefore denies them.

226. On information and belief, upon FDA approval of the Novitium ANDA, Novitium will market and distribute the Novitium ANDA Products to resellers, pharmacies, health care professionals, and end users of the Novitium ANDA Products. Accompanying the Novitium ANDA Products, Novitium will also knowingly and intentionally include a product label and insert containing instructions for administering the Novitium ANDA Products. Accordingly, Novitium will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Novitium ANDA Products to directly infringe the '197 patent. In addition, on information and belief, Novitium will encourage acts of direct infringement with knowledge of the '197 patent and knowledge that it is encouraging infringement. Novitium's conduct would intentionally actively induce and/or contribute to the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 226, and therefore denies them.

227. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218495, Novitium will make, use, offer to sell, or sell the Novitium ANDA Products within the United States, or will import the Novitium ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 227, and therefore denies them.

228. Novitium had actual knowledge of the '197 patent prior to submitting the Novitium ANDA and was aware that the submission of the Novitium ANDA with the request for FDA

approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 228, and therefore denies them.

229. Novitium submitted the Novitium ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Novitium ANDA Products. Novitium's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 229, and therefore denies them.

230. Plaintiffs will be irreparably harmed if Novitium is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Novitium, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 230, and therefore denies them.

COUNT VIII
INFRINGEMENT OF THE '430 PATENT BY NOVITIUM

231. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

232. On information and belief, Novitium has submitted or caused the submission of the Novitium ANDA to FDA and continues to seek FDA approval of the Novitium ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 232, and therefore denies them.

233. Plaintiffs own all rights, title, and interest in and to the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 233, and therefore denies them.

234. On information and belief, Novitium has infringed one or more claims of the '430 patent, including at least Claim 3 of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 234, and therefore denies them.

235. On information and belief, Novitium has infringed the '430 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Novitium ANDA and seeking FDA approval of the Novitium ANDA prior to the expiration of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 235, and therefore denies them.

236. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novitium ANDA Products prior to the expiration of the '430 patent would infringe the '430 patent under 35 U.S.C. § 271(a), and/or Novitium would induce the infringement of and/or contribute to the infringement of the '430 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 236, and therefore denies them.

237. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Novitium ANDA Products in the United States, including in the State of Delaware, would directly infringe the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 237, and therefore denies them.

238. On information and belief, upon FDA approval of the Novitium ANDA, Novitium will market and distribute the Novitium ANDA Products to resellers, pharmacies, health care professionals, and end users of the Novitium ANDA Products. Accompanying the Novitium ANDA Products, Novitium will also knowingly and intentionally include a product label and insert containing instructions for administering the Novitium ANDA Products. Accordingly, Novitium will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Novitium a ANDA Products to directly infringe the '430 patent. In addition, on information and belief, Novitium will encourage acts of direct infringement with knowledge of the '430 patent

and knowledge that it is encouraging infringement. Novitium's conduct would intentionally actively induce and/or contribute to the infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 238, and therefore denies them.

239. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218495, Novitium will make, use, offer to sell, or sell the Novitium ANDA Products within the United States, or will import the Novitium ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 239, and therefore denies them.

240. Novitium had actual knowledge of the '430 patent prior to submitting the Novitium ANDA, was aware that the submission of the Novitium ANDA with the request for FDA approval prior to the expiration of the '430 patent would constitute an act of infringement of the '430 patent, and was aware that use of the Novitium ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 240, and therefore denies them.

241. Novitium submitted the Novitium ANDA without a reasonable basis for asserting the '430 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Novitium ANDA Products. Novitium's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '430 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 241, and therefore denies them.

242. Plaintiffs will be irreparably harmed if Novitium is not enjoined from infringing the '430 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Novitium, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 242, and therefore denies them.

COUNT IX
INFRINGEMENT OF THE '947 PATENT BY ZENARA

243. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

244. On information and belief, Zenara has submitted or caused the submission of the Zenara ANDA to FDA and continues to seek FDA approval of the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 244, and therefore denies them.

245. Plaintiffs own all rights, title, and interest in and to the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 245, and therefore denies them.

246. On information and belief, Zenara has infringed one or more claims of the '947 patent, including at least Claim 13 of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 246, and therefore denies them.

247. According to Zenara's Notice Letter, the Zenara ANDA Products contain pitolisant hydrochloride.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 247, and therefore denies them.

248. On information and belief, Zenara has infringed the '947 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Zenara ANDA and seeking FDA approval of the Zenara ANDA prior to the expiration of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 248, and therefore denies them.

249. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Zenara ANDA Products prior to the expiration of the '947 patent would infringe the '947 patent under 35 U.S.C. § 271(a), and/or Zenara would induce the infringement of and/or contribute to the infringement of the '947 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 249, and therefore denies them.

250. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Zenara ANDA Products in the United States, including in the State of Delaware, would directly infringe the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 250, and therefore denies them.

251. On information and belief, upon FDA approval of the Zenara ANDA, Zenara will market and distribute the Zenara ANDA Products to resellers, pharmacies, health care professionals, and end users of the Zenara ANDA Products. Accompanying the Zenara ANDA Products, Zenara will also knowingly and intentionally include a product label and insert containing instructions for administering the Zenara ANDA Products. Accordingly, Zenara will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Zenara ANDA Products to directly infringe the '947 patent. In addition, on information and belief, Zenara will encourage acts of direct infringement with knowledge of the '947 patent and knowledge that it is encouraging infringement. Zenara's conduct would intentionally actively induce and/or contribute to the infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 251, and therefore denies them.

252. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218796, Zenara will make, use, offer to sell, or sell the Zenara ANDA Products within the United States, or will import the Zenara ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the claims of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 252, and therefore denies them.

253. Zenara had actual knowledge of the '947 patent prior to submitting the Zenara ANDA, was aware that the submission of the Zenara ANDA with the request for FDA approval prior to the expiration of the '947 patent would constitute an act of infringement of the '947 patent,

and was aware that use of the Zenara ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '947 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 253, and therefore denies them.

254. Zenara submitted the Zenara ANDA without a reasonable basis for asserting the '947 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Zenara ANDA Products. Zenara's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '947 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 254, and therefore denies them.

255. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing the '947 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Zenara, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 255, and therefore denies them.

COUNT X
INFRINGEMENT OF THE '197 PATENT BY ZENARA

256. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

257. On information and belief, Zenara has submitted or caused the submission of the Zenara ANDA to FDA and continues to seek FDA approval of the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 257, and therefore denies them.

258. Plaintiffs own all rights, title, and interest in and to the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 258, and therefore denies them.

259. On information and belief, Zenara has infringed one or more claims of the '197 patent, including at least Claim 1 of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 259, and therefore denies them.

260. On information and belief, Zenara has infringed the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Zenara ANDA and seeking FDA approval of the Zenara ANDA prior to the expiration of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 260, and therefore denies them.

261. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Zenara ANDA Products prior to the expiration of the '197 patent would infringe the '197 patent under 35 U.S.C. § 271(a), and/or Zenara would induce the infringement of and/or contribute to the infringement of the '197 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 261, and therefore denies them.

262. On information and belief, if the Zenara ANDA is approved, Zenara and its affiliates will make, offer for sale, sell, or otherwise distribute the Zenara ANDA Products in the United States, including in the State of Delaware, directly infringing the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 262, and therefore denies them.

263. On information and belief, upon FDA approval of the Zenara ANDA, Zenara will market and distribute the Zenara ANDA Products to resellers, pharmacies, health care professionals, and end users of the Zenara ANDA Products. Accompanying the Zenara ANDA Products, Zenara will also knowingly and intentionally include a product label and insert containing instructions for administering the Zenara ANDA Products. Accordingly, Zenara will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Zenara ANDA Products to directly infringe the '197 patent. In addition, on information and belief, Zenara will encourage acts of direct infringement with knowledge of the '197 patent and

knowledge that it is encouraging infringement. Zenara's conduct would intentionally actively induce and/or contribute to the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 263, and therefore denies them.

264. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218796, Zenara will make, use, offer to sell, or sell the Zenara ANDA Products within the United States, or will import the Zenara ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 264, and therefore denies them.

265. Zenara had actual knowledge of the '197 patent prior to submitting the Zenara ANDA and was aware that the submission of the Zenara ANDA with the request for FDA approval prior to the expiration of the '197 patent would constitute an act of infringement of the '197 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 265, and therefore denies them.

266. Zenara submitted the Zenara ANDA without a reasonable basis for asserting the '197 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Zenara ANDA Products. Zenara's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '197 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 266, and therefore denies them.

267. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing the '197 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Zenara, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 267, and therefore denies them.

COUNT XI
INFRINGEMENT OF THE '430 PATENT BY ZENARA

268. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Insofar as Plaintiffs incorporate the allegations of the preceding paragraphs of the Complaint, Defendant Annora repeats and realleges its responses thereto, as if fully set forth herein.

269. On information and belief, Zenara has submitted or caused the submission of the Zenara ANDA to FDA and continues to seek FDA approval of the Zenara ANDA.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 269, and therefore denies them.

270. Plaintiffs own all rights, title, and interest in and to the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 270, and therefore denies them.

271. On information and belief, Zenara has infringed one or more claims of the '430 patent, including at least Claim 3 of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 271, and therefore denies them.

272. On information and belief, Zenara has infringed the '430 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Zenara ANDA and seeking FDA approval of the Zenara ANDA prior to the expiration of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 272, and therefore denies them.

273. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Zenara ANDA Products prior to the expiration of the '430 patent would infringe the '430

patent under 35 U.S.C. § 271(a), and/or Zenara would induce the infringement of and/or contribute to the infringement of the '430 patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 273, and therefore denies them.

274. On information and belief, the importation, manufacture, sale, offer for sale, or use of the Zenara ANDA Products in the United States, including in the State of Delaware, would directly infringe the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 274, and therefore denies them.

275. On information and belief, upon FDA approval of the Zenara ANDA, Zenara will market and distribute the Zenara ANDA Products to resellers, pharmacies, health care professionals, and end users of the Zenara ANDA Products. Accompanying the Zenara ANDA Products, Zenara will also knowingly and intentionally include a product label and insert containing instructions for administering the Zenara ANDA Products. Accordingly, Zenara will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Zenara a ANDA Products to directly infringe the '430 patent. In addition, on information and belief, Zenara will encourage acts of direct infringement with knowledge of the '430 patent and knowledge that it is encouraging infringement. Zenara's conduct would intentionally actively induce and/or contribute to the infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 275, and therefore denies them.

276. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 218796, Zenara will make, use, offer to sell, or sell the Zenara ANDA Products within the United States, or will import the Zenara ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 276, and therefore denies them.

277. Zenara had actual knowledge of the '430 patent prior to submitting the Zenara ANDA, was aware that the submission of the Zenara ANDA with the request for FDA approval prior to the expiration of the '430 patent would constitute an act of infringement of the '430 patent,

and was aware that use of the Zenara ANDA Products in accordance with its proposed labeling and/or packet insert would constitute an act of infringement of the '430 patent.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 277, and therefore denies them.

278. Zenara submitted the Zenara ANDA without a reasonable basis for asserting the '430 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Zenara ANDA Products. Zenara's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '430 patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 278, and therefore denies them.

279. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing the '430 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Zenara, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Defendant Annora lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 279, and therefore denies them.

PRAYER FOR RELIEF

Defendant Annora denies that Plaintiffs are entitled to any of the relief requested against the Annora Defendants in Paragraphs B, F, J, N, R, V, Y and Z of the Prayer for Relief section of the Complaint and deny that Plaintiffs are entitled to any of the relief requested in the remaining Paragraphs of the Prayer for Relief section of the Complaint only to the extent those Paragraphs purport to seek relief against Defendant Annora .

GENERAL DENIAL

To the extent not specifically admitted above, including but not limited to every instance where Defendant Annora is without knowledge or information sufficient to form a belief about the truth of the allegations, Defendant Annora denies all allegations of the Complaint, including all headings to the extent the headings may be deemed allegations.

DEFENSES AND AFFIRMATIVE DEFENSES

Without any admissions as to the burdens of proof, or as to any of the allegations in the Complaint, Defendant Annora states the following:

First Affirmative Defense
Failure to State a Claim

Plaintiffs' Complaint, in whole or in part, fails to state claims upon which relief may be granted.

Second Affirmative Defense
Non-Infringement of the '947 Patent

The submission of ANDA No. 218832 to the FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '947 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Third Affirmative Defense
Non-Infringement of the '197 Patent

The submission of ANDA No. 218832 to the FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '197 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fourth Affirmative Defense
Non-Infringement of the '430 Patent

The submission of ANDA No. 218832 to the FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '430 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fifth Affirmative Defense
Invalidity of the '947 Patent

The claims of the '947 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Sixth Affirmative Defense
Invalidity of the '197 Patent

The claims of the '197 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Seventh Affirmative Defense
Invalidity of the '430 Patent

The claims of the '430 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Eighth Affirmative Defense
No Costs

Upon information and belief, Plaintiffs are barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

Ninth Affirmative Defense
Failure to State Claim of Willfulness

Plaintiffs fail to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

RESERVATION OF DEFENSES

Defendant Annora reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, the defense of unenforceability.

COUNTERCLAIMS

For its counterclaims against Harmony Biosciences, LLC ("Harmony"), Bioprojet Société Civile de Recherche ("Bioprojet SCR"), and Bioprojet Pharma SAS ("Bioprojet Pharam") (collectively "Counterclaim Defendants"), Annora Pharma Private Limited ("Counterclaimant Annora") states as follows:

The Parties

1. Annora Pharma Private Limited is a company organized and existing under the laws of the Republic of India with its principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State, 502313, India.

2. On information and belief, based on Counterclaim Defendants' allegation, Harmony Biosciences, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 630 W Germantown Pike, Suite 215, Plymouth Meeting, PA 19462, USA.

3. On information and belief, based on Counterclaim Defendants' allegation, Bioprojet Société Civile de Recherche is an independent, privately owned company organized and existing under the laws of France, having a place of business at 7, rue Rameau, 75002, Paris, France.

4. On information and belief, based on Counterclaim Defendants' allegation, Bioprojet Pharma SAS is a wholly owned subsidiary of Bioprojet Société Civile de Recherche, existing under the laws of France, having a place of business at 9, rue Rameau, 75002, Paris, France.

Nature of the Action

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

6. Counterclaimant Annora seeks a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent Nos. 8,486,947 ("the '947 patent"), 8,207,197 ("the '197 patent"), and 8,354,430 ("the '430 patent"), and (collectively, "the Patents-in-Suit"), literally or under the doctrine of equivalents.

7. Counterclaimant Annora also seeks a declaration that the claims of the Patents-in-Suit are invalid under one or more sections of 35 U.S.C. § 101 *et seq*.

8. As a consequence of Counterclaim Defendants' Complaint against Counterclaimant Annora, and based on Annora's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendants and Counterclaimant Annora having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the Patents-in-Suit.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Counterclaim Defendants have submitted to this Court's personal jurisdiction by suing Counterclaimant Annora in this District. On information and belief, Counterclaim Defendants sell products in this District, including the WAKIX® (pitolisant hydrochloride) product

at issue in this case, and conduct substantial business in, and have regular and systemic contacts with, this District.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

12. Harmony Biosciences, LLC is the holder of New Drug Application ("NDA") No. 211150 for WAKIX® (pitolisant hydrochloride) tablets.

13. The Patents-in-Suit are listed in the Orange Book for WAKIX®.

14. The face of the '947 patent, titled "Treatment of Parkinson's Disease, Obstructive Sleep Apnea, Dementia With Lewy Bodies, Vascular Dementia With Non-imidazole Alkylamines Histamine H3-receptor Ligands," states that it issued on July 16, 2013.

15. Based on the face of the '947 patent, and on information and belief, Bioprojet SCR is the assignee of the '947 patent.

16. The face of the '197 patent, titled "Monohydrochloride salt of 1-[3-[3-(4-Chlorophenyl) Propoxy] Propyl] -Piperidine," states that it issued on June 26, 2012.

17. Based on the face of the '197 patent, and on information and belief, Bioprojet SCR is the assignee of the '197 patent.

18. The face of the '430 patent, titled "Monohydrochloride salt of 1-[3-[3-(4-Chlorophenyl) Propoxy] Propyl] -Piperidine," states that it issued on January 15, 2013.

19. Based on the face of the '430 patent, and on information and belief, Bioprojet SCR is the assignee of the '430 patent.

20. Annora submitted ANDA No. 218831 to the FDA seeking approval for a proposed drug product, namely 4.45 mg and 17.8 mg pitolisant tablets ("Proposed ANDA Product"), before the expiration of the Patents-in-Suit.

21. By a letter dated October 16, 2023 ("Notice Letter"), Counterclaimant Annora notified Counterclaim Defendants of the filing of ANDA No. 218832 with certifications provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of each of the Patents-in-Suit is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

22. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of each of the Patents-in-Suit is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

23. The Notice Letter also included an Offer of Confidential Access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

24. Counterclaim Defendants did not accept the OCA.

25. Counterclaim Defendants filed suit on November 21, 2023, alleging that Counterclaimant Annora infringed the Patents-in-Suit without having reviewed ANDA No. 218832.

First Counterclaim
Declaratory Judgment of Non-Infringement of the '947 Patent

26. Counterclaimant Annora realleges Paragraphs 1-25 as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding non-infringement of the '947 patent.

28. Counterclaim Defendants have accused Counterclaimant Annora of infringing the '947 patent in connection with submission of ANDA No. 218832 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 218832 is approved.

29. The submission of ANDA No. 218832 to the FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '947 patent, either literally or under the doctrine of equivalents.

30. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 218832 have not and would not infringe, direct or indirectly, any valid and enforceable claim of the '947 patent, either literally or under the doctrine of equivalents.

31. Because Counterclaimant Annora has not infringed and will not infringe any valid and enforceable claim of the '947 patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Counterclaimant Annora.

32. Counterclaimant Annora is entitled to a declaration that the submission of ANDA No. 218832 to the FDA does not infringe any valid and enforceable claim of the '947 patent.

33. Further, Counterclaimant Annora is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '947 patent.

Second Counterclaim
Declaratory Judgment of Non-Infringement of the '197 Patent

34. Counterclaimant Annora reallege Paragraphs 1-33 as if fully set forth herein.

35. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding non-infringement of the '197 patent.

36. Counterclaim Defendants have accused Counterclaimant Annora of infringing the '197 patent in connection with submission of ANDA No. 218832 and in connection with the

prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 218832 is approved.

37. The submission of ANDA No. 218832 to the FDA does not infringe, direct or indirectly, any valid and enforceable claim of the '197 patent, either literally or under the doctrine of equivalents.

38. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 218832 have not infringed and would not infringe, directly or indirectly, any valid and enforceable claim of the '197 patent, either literally or under the doctrine of equivalents.

39. Because Counterclaimant Annora has not infringed and will not infringe any valid and enforceable claim of the '197 patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Counterclaimant Annora.

40. Counterclaimant Annora is entitled to a declaration that the submission of ANDA No. 218832 to the FDA does not infringe any valid and enforceable claim of the '197 patent.

41. Further, Counterclaimant Annora is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '197 patent.

Third Counterclaim
Declaratory Judgment of Non-Infringement of the '430 Patent

42. Counterclaimant Annora realleges Paragraphs 1-41 as if fully set forth herein.

43. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding non-infringement of the '430 patent.

44. Counterclaim Defendants have accused Counterclaimant Annora of infringing the '430 patent in connection with submission of ANDA No. 218832 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 218832 is approved.

45. The submission of ANDA No. 218832 to the FDA does not infringe, direct or indirectly, any valid and enforceable claim of the '430 patent, either literally or under the doctrine of equivalents.

46. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 218832 have not and would not infringe, directly or indirectly, any valid and enforceable claim of the '430 patent, either literally or under the doctrine of equivalents.

47. Because Counterclaimant Annora has not infringed and will not infringe any valid and enforceable claim of the '430 patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Annora.

48. Counterclaimant Annora is entitled to a declaration that the submission of ANDA No. 218832 to the FDA does not infringe any valid and enforceable claim of the '430 patent.

49. Further, Counterclaimant Annora is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '430 patent.

Fourth Counterclaim
Declaratory Judgment of Invalidity of the '947 Patent

50. Counterclaimant Annora reallege Paragraphs 1-49 as if fully set forth herein.

51. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding invalidity of the '947 patent.

52. The '947 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq*., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

53. Counterclaimant Annora is entitled to a judicial declaration that the '947 patent is invalid.

Fifth Counterclaim
Declaratory Judgment of Invalidity of the '197 Patent

54. Counterclaimant Annora realleges Paragraphs 1-53 as if fully set forth herein.

55. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding invalidity of the '197 patent.

56. The '197 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq*., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

57. Counterclaimant Annora is entitled to a judicial declaration that the '197 patent is invalid.

Sixth Counterclaim
Declaratory Judgment of Invalidity of the '430 Patent

58. Counterclaimant Annora realleges Paragraphs 1-57 as if fully set forth herein.

59. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Annora and Counterclaim Defendants regarding invalidity of the '430 patent.

60. The '430 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq*., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

61. Counterclaimant Annora is entitled to a judicial declaration that the '430 patent is invalid.

Prayer for Relief

WHEREFORE, Counterclaimant Annora respectfully requests that the Court award the following relief:

A. A declaration that by filing ANDA No. 218832, Counterclaimant Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, and that Counterclaimant Annora has a lawful right to obtain FDA approval of its ANDA No. 218832 for pitolisant hydrochloride tablets;

B. A declaration that Counterclaimant Annora will not directly infringe, or contribute to or induce infringement of any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale, or sale of the pitolisant hydrochloride tablets that are the subject of ANDA No. 218832;

C. A declaration that the Patents-in-Suit are invalid;

D. An injunction against Counterclaim Defendants, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating

infringement litigation against Counterclaimant Annora or its customers, suppliers, or any prospective or present sellers, distributors, or customers of Counterclaimant Annora, or charging them either verbally or in writing with infringement of the Patents-in-Suit with respect to the pitolisant hydrochloride tablets, that are the subject of ANDA No. 218832;

E. A declaration that this is an exceptional case, and that the Counterclaimant Annora be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285;

F. A declaration that Counterclaim Defendants are entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Counterclaimant Annora for infringement of the Patents-in-Suit;

G. An award of costs and expenses to Counterclaimant Annora; and

H. An award to Counterclaimant Annora of such further relief as this Court may deem necessary, just, and proper.

Dated: March 4, 2024

Respectfully submitted,

BENESCH FRIEDLANDER
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Attorneys for Defendant Annora Pharma Private Limited

CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2024, a copy of the foregoing *Defendant Annora Pharma Private Limited's Answer to Plaintiffs' Complaint with Affirmative Defenses and Counterclaims* was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's CM/ECF system.

/s/ Kristen Cramer
Kristen Cramer (#4512)

Attorney for Defendant Annora Pharma Private Limited