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.	)	C.A. No. _____
AET PHARMA US, INC., ANNORA PHARMA PRIVATE LIMITED, HETERO USA, INC., HETERO LABS LIMITED, NOVITIUM PHARMA LLC, ZENARA PHARMA PRIVATE LIMITED and BIOPHORE INDIA PHARMACEUTICALS PRIVATE LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Harmony Biosciences, LLC ("Harmony"), Bioprojet Société Civile de Recherche ("Bioprojet SCR"), and Bioprojet Pharma SAS ("Bioprojet Pharma") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants AET Pharma US, Inc., ("AET"); Annora Pharma Private Limited, Hetero USA, Inc., and Hetero Labs Limited (collectively, "Annora"); Novitium Pharma LLC ("Novitium"); and Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited (collectively "Zenara"), and hereby allege as follows:

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").

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.

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.

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

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.

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.

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).

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 H_3-Receptor Ligands," and was duly and lawfully issued by the USPTO on July 16, 2013. The '947 patent is attached hereto as Exhibit A.

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.

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.

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®.

THE 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.

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.

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.

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.

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.

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.

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.

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.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

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

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.

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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").

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

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

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."

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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").

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

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

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

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."

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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").

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

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

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

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."

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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").

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

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

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."

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.

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.

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.

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.

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).

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).

COUNT I
INFRINGEMENT OF THE '947 PATENT BY AET

138. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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

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.

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).

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.

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.

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.

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.

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 non-infringement with respect to the ’947 patent renders this case “exceptional” under 35 U.S.C. § 285.

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.

COUNT II
INFRINGEMENT OF THE ’197 PATENT BY AET

152. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT III
INFRINGEMENT OF THE '947 PATENT BY ANNORA

165. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT IV
INFRINGEMENT OF THE '197 PATENT BY ANNORA

179. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT V
INFRINGEMENT OF THE '430 PATENT BY ANNORA

192. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT VI
INFRINGEMENT OF THE '947 PATENT BY NOVITIUM

205. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT VII
INFRINGEMENT OF THE '197 PATENT BY NOVITIUM

219. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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.

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).

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.

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.

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.

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.

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.

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.

COUNT VIII
INFRINGEMENT OF THE '430 PATENT BY NOVITIUM

231. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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.

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).

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.

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.

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.

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.

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.

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.

COUNT IX
INFRINGEMENT OF THE '947 PATENT BY ZENARA

243. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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

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.

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).

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.

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.

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.

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.

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.

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.

COUNT X
INFRINGEMENT OF THE '197 PATENT BY ZENARA

256. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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.

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).

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.

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.

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.

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.

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.

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.

COUNT XI
INFRINGEMENT OF THE '430 PATENT BY ZENARA

268. Plaintiffs incorporate by reference the foregoing paragraphs 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.

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

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.

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.

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).

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.

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.

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.

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that AET has infringed one or more claims of the '947 and '197 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Annora has infringed one or more claims of the '947, '197, and '430 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that Novitium has infringed one or more claims of the '947, '197, and '430 patents under 35 U.S.C. § 271(e)(2)(A);

D. A judgment that Zenara has infringed one or more claims of the '947, '197, and '430 patents under 35 U.S.C. § 271(e)(2)(A);

E. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), AET's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the AET ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947 and '197 patents;

F. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), Annora's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Annora ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947, '197, and '430 patents;

G. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), Novitium's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Novitium ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947, '197, and '430 patents;

H. A judgment that, under one or more of 35 U.S.C. § 271(a), (b), and/or (c), Zenara's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Zenara ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '947, '197, and '430 patents;

I. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of AET's ANDA No. 218892 shall be no earlier than the expiration date of the '947 and '197 patents, or any later expiration of exclusivity for the '947 and '197 patents, including any extensions or regulatory exclusivities;

J. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Annora's ANDA No. 218832 shall be no earlier than the expiration date of the '947, '197, and '430 patents, or any later expiration of exclusivity for the '947, '197, and '430 patents, including any extensions or regulatory exclusivities;

K. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Novtium's ANDA No. 218495 shall be no earlier than the expiration date

of the ’947, ’197, and ’430 patents, or any later expiration of exclusivity for the ’947, ’197, and ’430 patents including any extensions or regulatory exclusivities;

L. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Zenara’s ANDA No. 218796 shall be no earlier than the expiration date of the ’947, ’197, and ’430 patents, or any later expiration of exclusivity for the ’947, ’197, and ’430 patents including any extensions or regulatory exclusivities;

M. A permanent injunction restraining and enjoining AET, its affiliates and subsidiaries, and all persons and entities acting in concert with AET, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the AET ANDA Products, until the day after expiration of the ’947 and ’197 patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’947 and ’197 patents.

N. A permanent injunction restraining and enjoining Annora, its affiliates and subsidiaries, and all persons and entities acting in concert with Annora, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the Annora ANDA Products, until the day after expiration of the ’947, ’197, and ’430 patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’947, ’197, and ’430 patents.

O. A permanent injunction restraining and enjoining Novitium, its affiliates and subsidiaries, and all persons and entities acting in concert with Novitium, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the Novitium ANDA Products, until the day after expiration of the ’947, ’197, and ’430 patents, including any

additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '947, '197, and '430 patents.

P. A permanent injunction restraining and enjoining Zenara, its affiliates and subsidiaries, and all persons and entities acting in concert with Zenara, from commercially manufacturing, using, offering for sale, or selling or importing into the United States the Zenara ANDA Products, until the day after expiration of the '947, '197, and '430 patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '947, '197, and '430 patents.

Q. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if AET engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the AET ANDA Products, or any product that infringes the '947 or '197 patents, or induces or contributes to such conduct, prior to the expiration of the '947 or '197 patents, or any later expiration of exclusivity for the '947 or '197 patents, including any extensions or regulatory exclusivities;

R. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Annora engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Products, or any product that infringes the '947, '197, or '430 patents, or induces or contributes to such conduct, prior to the expiration of the '947, '197, or '430 patents, or any later expiration of exclusivity for the '947, '197, or '430 patents, including any extensions or regulatory exclusivities;

S. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Novitium engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium ANDA Products, or any product that infringes the '947, '197, or '430 patents, or induces or contributes to such conduct, prior to the expiration of the '947, '197, or '430 patents,

or any later expiration of exclusivity for the '947, '197, or '430 patents, including any extensions or regulatory exclusivities;

T. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Zenara engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zenara ANDA Products, or any product that infringes the '947, '197, or '430 patents, or induces or contributes to such conduct, prior to the expiration of the '947, '197, or '430 patents, or any later expiration of exclusivity for the '947, '197, or '430 patents, including any extensions or regulatory exclusivities;

U. The entry of a judgment declaring that AET's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

V. The entry of a judgment declaring that Annora's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

W. The entry of a judgment declaring that Novitium's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

X. The entry of a judgment declaring that Zenara's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

Y. An award to Plaintiffs of their costs and expenses in this action; and

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

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