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., AET LABORATORIES PRIVATE LIMITED, and ALFRED E. TIEFENBACHER (GMBH & CO. KG)	)	
Defendants.	)	

COMPLAINT

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 Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) (collectively, "AET"), 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 submission of Abbreviated New Drug Applications ("ANDA") No. 218892 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") and 8,207,197 ("the '197 patent") (collectively, "the Asserted Patents").

2. On November 21, 2023, Plaintiffs filed related action *Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-cv-1340 (JLH) (D. Del.) against, *inter alia,* AET Pharma US, Inc. for patent infringement of the Asserted Patents arising from its ANDA No. 218892 submission. This action arises from Plaintiffs' recent receipt of an additional notice of purported Paragraph IV certifications from AET for the Asserted Patents.

WAKIX® AND THE ASSERTED PATENTS

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

4. 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.

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

6. 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.

7. 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.

8. 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).

9. 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.

10. 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.

11. The Asserted 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 Asserted Patents 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 Asserted Patents.

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 Laboratories Private Limited is a corporation existing under the laws of the Republic of India, having a place of business at Survey No. 42, Gaddapotharam Village, Kazipally Industrial Area, Sangareddy District, Telangana State, 502319, India.

17. On information and belief, Alfred E. Tiefenbacher (GmbH & Co. KG) is a corporation organized and existing under the laws of Germany, having a place of business at Van-der-Smissen Strasse 1, 22767 Hamburg, Germany.

18. On information and belief, Alfred E. Tiefenbacher (GmbH & Co. KG) is the parent company of AET Pharma US, Inc. and AET Laboratories Private Limited. Alfred E. Tiefenbacher (GmbH & Co. KG) refers to AET Pharma US, Inc. and AET Laboratories Private Limited as part of the Tiefenbacher Group.[1]

19. On information and belief, Alfred E. Tiefenbacher (GmbH & Co. KG) ultimately owns ANDA No. 218892.

20. On information and belief, AET Pharma US, Inc. and AET Laboratories Private Limited act at the direction, and for the benefit, of Alfred E. Tiefenbacher (GmbH & Co. KG), and each is controlled and/or dominated by Alfred E. Tiefenbacher (GmbH & Co. KG).

[1] *See* Ex. C, Tiefenbacher Group, "Organization Structure," https://tiefenbacher-pharmaceuticals.com/about-us/#company *(last accessed 8/13/2024)*; Ex. D, Tiefenbacher Group, "AET Pharma US Inc., a part of Tiefenbacher Group, announces successful approval of Abbreviated New Drug Application (ANDA) for Posaconazole," https://tiefenbacher-pharmaceuticals.com/2021/02/08/tiefenbacher-abbreviated-new-drug-application-anda-posaconazole/ (*last accessed 8/13/2024)*

21. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) 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.

22. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products in the United States.

23. For example, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) collaborated with regard to the development, regulatory approval, and manufacture of the generic posaconazole product subject to ANDA No. 213454. Alfred E. Tiefenbacher (GmbH & Co. KG) issued a press release dated February 8, 2021 which is still available on its website and states, "AET Pharma US Inc., part of the Tiefenbacher Group, announces successful approval of Abbreviated New ANDA Drug Application (ANDA) for Posaconazole."[2]

24. The press release further states that AET's generic posaconazole product was developed by and is manufactured at AET's facility in Hyderabad, India. The label for AET Pharma US Inc.'s approved posaconazole ANDA product identifies "AET Laboratories Private Limited" as the drug product manufacturer.[3] The Tiefenbacher Group website memorializes the

[2] *See* Ex. D

[3] *See* Ex. E, NIH Library of Medicine, DailyMed, "Label: Posaconazole tablet, delayed release," https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=548124ce-8050-46a9-967b-ff23dfb18633 (*last accessed 8/13/2024)*

"Opening of AET Laboratories India (R&D and Manufacturing)," and shows that the manufacturing facility referred to is AET Laboratories Private Limited.[4]

25. On information and belief, AET Laboratories Private Limited develops, manufactures, tests, packages, stores, and releases generic solid oral dosage forms for sale in the United States and provides information for regulatory submissions to obtain approval for such generic products.

26. On information and belief, the Tiefenbacher Group sometimes refers to AET Laboratories Private Limited as Tiefenbacher Laboratories or AET Laboratories India.

27. In *Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-cv-1340 (JLH) (D. Del.), counsel for AET Pharma US, Inc. represented that "AET Pharma US was not involved in research and development of the ANDA Products, API selection, and testing . . . ." On information and belief, tasks necessary for preparation and submission of ANDA No. 218892, such as the research and development of the ANDA Products, API selection, and testing were performed by other entities in the Tiefenbacher Group, specifically, AET Laboratories Private Limited.

28. AET's 2024 Product List indicates that AET's generic pitolisant tablets were developed "in-house" and will be manufactured in a Zone IVb environment.[5] On information and belief, India is a Zone IVb environment. Tiefenbacher Laboratories (*i.e.*, AET Laboratories Private Limited) in Hyderabad, India is the only facility identified in AET's 2024 Product List as an FDA-

[4] *See* Ex. F, Tiefenbacher Group, "Opening of AET Laboratories India (R&D and Manufacturing)," https://tiefenbachergroup.com/timeline/opening-of-aet-labs-india-2/ *(last accessed 8/13/2024)*

[5] *See* Ex. G, Tiefenbacher Group, "Tiefenbacher FDF Product List," https://tiefenbacher-pharmaceuticals.com/wp-content/uploads/2024/04/TIEFENBACHER-FDF-PRODUCT-LIST-2024.pdf *(last accessed 8/13/2024)*

approved manufacturing facility, indicating that it is the AET manufacturing facility used for the generic pitolisant tablet products intended for the United States market.

29. On information and belief and according to AET's 2024 Product List, AET Laboratories Private Limited was and is involved in the development and manufacture of AET's generic pitolisant tablets.

30. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) caused ANDA No. 218892 ("AET ANDA") to be submitted to FDA and seek approval of that application to permit AET to market generic versions of WAKIX® tablets in the United States.

31. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) acted collaboratively in the preparation and submission of ANDA No. 218892 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218892 and seeking to market the proposed generic pitolisant hydrochloride tablets described in the application.

32. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) intend 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.

33. On information and belief, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) rely on material assistance from each other to obtain regulatory approval for, develop, manufacture, 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, AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the AET ANDA Products, in the event FDA approves the AET ANDA.

JURISDICTION AND VENUE

34. 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 Asserted Patents. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

35. 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).

36. Additionally, this Court has personal jurisdiction over AET Pharma US, Inc., AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) because, on information and belief, each 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.

37. 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.

38. On or about July 4, 2024, the Tiefenbacher Group touted on its website its efforts to expand its relationship with customers and partners in the United States.[6]

39. 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.

40. AET has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of one or more of the Asserted Patents that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by letters dated October 14, 2023 ("AET's October 14, 2023 Notice Letter") and August 7, 2024 ("AET's August 7, 2024 Notice Letter") sent by AET to Harmony and Bioprojet pursuant to 21 U.S.C. § 355(j)(2)(B), AET prepared and filed the AET ANDA with the intention of seeking to market the AET ANDA Products nationwide, including in Delaware.

41. 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.

42. 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 channels of distribution in Delaware for the sale of the AET ANDA Products.

[6] *See* Ex. H, Tiefenbacher Group,"Tiefenbacher Group Celebrating US Independence Day," https://tiefenbacher-pharmaceuticals.com/2024/07/04/tiefenbacher-group-celebrating-us-independence-day/ *(last accessed 8/13/2024)*

43. Alternatively, this Court has personal jurisdiction over AET Laboratories Private Limited and Alfred E. Tiefenbacher (GmbH & Co. KG) 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 AET 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 AET Laboratories Private Limited, and Alfred E. Tiefenbacher (GmbH & Co. KG) satisfies due process.

44. Venue is proper in this district for AET Pharma US, 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.

45. Venue is proper in this district for AET Laboratories Private Limited and Alfred E. Tiefenbacher (GmbH & Co. KG) pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, *inter alia*, each is a foreign corporation and may be sued in any judicial district, and each is subject to personal jurisdiction in Delaware.

AET'S ANDA NO. 218892

46. 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 Asserted Patents.

47. 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 October 14, 2023 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 Asserted 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 Asserted Patents.

48. 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.

49. AET's October 14, 2023 Notice Letter did not dispute infringement of Claims 1–5 or 10–14 of the '947 patent.

50. AET's October 14, 2023 Notice Letter did not dispute infringement of any of the claims of the '197 patent.

51. On November 21, 2023, Plaintiffs filed related action *Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-cv-1340 (JLH) (D. Del.) against, *inter alia,* AET Pharma US, Inc. for patent infringement of the Asserted Patents arising from its ANDA No. 218892 submission. That case was consolidated with *Harmony Biosciences, LLC et al. v. Lupin Limited et al.*, C.A. No. 23-1286 (JLH) (D. Del).

52. AET sent a second Notice Letter to Harmony and Bioprojet dated August 7, 2024. AET's August 7, 2024 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 Asserted Patents listed in the Orange Book for WAKIX®. Thus, AET's purpose in submitting the AET ANDA remains to manufacture and market the AET ANDA Products before the expiration of the Asserted Patents.

53. AET's August 7, 2024 Notice Letter still does not dispute infringement of Claims 1–5 or 10–14 of the '947 patent.

54. AET's August 7, 2014 Notice Letter contained a purported offer of confidential access to ANDA No. 218892 that contained unreasonable restrictions regarding access to AET's ANDA, which were more restrictive than the terms of the Protective Order entered in *Harmony Biosciences, LLC et al. v. Lupin Limited et al.*, C.A. No. 23-1286 (JLH) (D. Del). The restrictions AET attempted to place 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."

55. On August 9, 2024, outside counsel for Plaintiffs requested that AET promptly produce ANDA No. 218892, including all supplements and amendments purportedly underlying the August 7, 2024 Notice Letter, along with the drug substance Drug Master File referenced in AET's ANDA, under the terms of the Protective Order entered in the related case *Harmony Biosciences, LLC et al. v. Lupin Limited et al.*, C.A. No. 23-1286 (JLH) (D. Del), D.I. 81. AET has not provided Plaintiffs with these materials as of the filing of this complaint and rejected Plaintiffs' request for a meet and confer on the topic.

56. 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.

57. 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.

58. If FDA approves the AET ANDA, the manufacture, use, offer for sale, sale, or importation of the AET ANDA Products will directly infringe the Asserted 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.

59. 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 Asserted 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 Asserted Patents, it will infringe, contribute to the infringement of, and/or induce the infringement of the Asserted Patents under one or more of 35 U.S.C. § 271(a), (b), and/or (c).

60. This action is being filed within forty-five days of Plaintiffs' receipt of AET's August 7, 2024 Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
INFRINGEMENT OF THE '947 PATENT BY AET

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

62. 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.

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

64. AET did not dispute infringement of Claims 1–5 and 10–14 of the '947 patent in its October 14, 2023 and August 7, 2024 Notice Letters. 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 Letters. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

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

66. According to AET's October 14, 2023 and August 7, 2024 Notice Letters, the AET ANDA Products contain pitolisant hydrochloride.

67. 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.

68. 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).

69. 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.

70. 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.

71. 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.

72. 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.

73. 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.

74. 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

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

76. 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.

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

78. AET did not dispute infringement of any claim of the '197 patent in its October 14, 2023 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 October 14, 2023 Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

79. On information and belief, AET has infringed at least claim 1 of the '197 patent.

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

81. 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).

82. 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.

83. 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.

84. 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.

85. 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.

86. 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'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.

87. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that AET has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A);

B. 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 Asserted Patents;

C. 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 Asserted Patents, or any later expiration of exclusivity for the Asserted Patents, including any extensions or regulatory exclusivities;

D. 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 Asserted Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the Asserted Patents.

E. 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 Asserted Patents, or induces or contributes to such conduct, prior to the expiration of the Asserted Patents or any later expiration of exclusivity for the Asserted Patents, including any extensions or regulatory exclusivities;

F. 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Christopher N. Sipes
Erica N. Andersen
Brianne (Bharkhda) Sullivan
Sarahi Uribe
Pierre Anquetil
Elaine Nguyen
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

August 13, 2024