IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., ABBVIE LTD., and NEUROCRINE BIOSCIENCES, INC., Plaintiffs, v. ALKEM LABORATORIES LIMITED, HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO USA INC., LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD., MSN LIFE SCIENCES PVT. LTD., MSN PHARMACEUTICALS INC., PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., SOLCO HEALTHCARE US, LLC., SANDOZ INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ZENARA PHARMA PRIVATE LIMITED and BIOPHORE INDIA PHARMACEUTICALS PRIVATE LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AbbVie Inc. and AbbVie Ltd. (together, "AbbVie"), and Neurocrine Biosciences, Inc. ("Neurocrine") (collectively, "Plaintiffs"), by their attorneys, bring this action against Defendants Alkem Laboratories Limited ("Alkem"); Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively, "Hetero"); Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Lupin"); MSN Laboratories Private Ltd. ("MSN Laboratories"), MSN Life Sciences Pvt. Ltd. ("MSN Life Sciences"), and MSN Pharmaceuticals Inc. ("MSN

Pharmaceuticals") (collectively, "MSN"); Prinston Pharmaceutical Inc. ("Prinston Pharmaceutical"), Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai"), and Solco Healthcare US, LLC ("Solco") (collectively, "Prinston"); Sandoz Inc. ("Sandoz"); Sun Pharmaceutical Industries Limited ("Sun"); Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals") and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva"); and Zenara Pharma Private Limited ("Zenara Pharma") and Biophore India Pharmaceuticals Private Ltd. ("Biophore") (collectively, "Zenara"), and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,056,927 ("the '927 patent"), 7,176,211 ("the '211 patent"), 7,419,983 ("the '983 patent"), 10,537,572 ("the '572 patent"), 10,682,351 ("the '351 patent"), and 11,344,551 ("the '551 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Alkem's, Hetero's, Lupin's, MSN's, Prinston's, Sandoz's, Sun's, Teva's, and Zenara's recent submissions to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Applications ("ANDA" or "ANDAs") seeking approval to market generic versions of Plaintiffs' commercial pharmaceutical product ORILISSA® (elagolix sodium oral tablets, (eq. 150 mg base and eq. 200 mg base), submitted under New Drug Application ("NDA") No. 210450), prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for ORILISSA®. Alkem has submitted ANDA No. 217668 ("Alkem's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Alkem's Generic Product"), prior to the expiration of the '572 patent, the '351 patent, and the '551 patent.

Hetero has submitted ANDA No. 217690 ("Hetero's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Hetero's Generic Product"), prior to the expiration of the '927 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent. Lupin has submitted ANDA No. 217712 ("Lupin's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Lupin's Generic Product"), prior to the expiration of the '927 patent, the '983 patent, '572 patent, the '351 patent, and the '551 patent. MSN has submitted ANDA No. 217716 ("MSN's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("MSN's Generic Product"), prior to the expiration of the '927 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent. Prinston has submitted ANDA No. 217296 ("Prinston's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Prinston's Generic Product"), prior to the expiration of the '927 patent, the '983 patent, and the '551 patent. Sandoz has submitted ANDA No. 217551 ("Sandoz's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Sandoz's Generic Product"), prior to the expiration of the '927 patent, the '211 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent. Sun has submitted ANDA No. 215804 ("Sun's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Sun's Generic Product"), prior to the expiration of the '927 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent. Teva has submitted ANDA No. 217642 ("Teva's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)

("Teva's Generic Product"), prior to the expiration of the '572 patent, the '351 patent, and the '551 patent. Zenara has submitted ANDA No. 217760 ("Zenara's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Zenara's Generic Product"), prior to the expiration of the '572 patent, the '351 patent, and the '551 patent.

2. Alkem has infringed one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217668 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof. Alkem will infringe one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Alkem's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof.

3. Hetero has infringed one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217690 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Hetero's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof. Hetero will infringe one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Hetero's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof.

4. Lupin has infringed one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217712 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Lupin's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof. Lupin will infringe one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Lupin's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof.

5. MSN has infringed one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217716 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof. MSN will infringe one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of MSN's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof.

6. Prinston has infringed one or more claims of the '927, '983, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217296 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Prinston's Generic Product prior to the expiration of the '927, '983, and '551 patents, or any extensions thereof. Prinston will infringe one or more claims of the '927, '983, and '551 patents

under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Prinston's Generic Product prior to the expiration of the '927, '983, and '551 patents, or any extensions thereof.

7. Sandoz has infringed one or more claims of the '927, '211, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217551 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Sandoz's Generic Product prior to the expiration of the '927, '211, '983, '572, '351, and '551 patents, or any extensions thereof. Sandoz will infringe one or more claims of the '927, '211, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Sandoz's Generic Product prior to the expiration of the '927, '211, '983, '572, '351, and '551 patents, or any extensions thereof.

8. Sun has infringed one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 215804 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Sun's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof. Sun will infringe one or more claims of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Sun's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents, or any extensions thereof.

9. Teva has infringed one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217642 seeking FDA approval for

the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof. Teva will infringe one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Teva's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof.

10. Zenara has infringed one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217760 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zenara's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof. Zenara will infringe one or more claims of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Zenara's Generic Product prior to the expiration of the '572, '351, and '551 patents, or any extensions thereof.

ORILISSA®

11. ORILISSA® is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Over 80,000 women have been prescribed ORILISSA®.

12. Endometriosis occurs when tissue that normally lines the inside of the uterus grows outside of the uterus (where it does not belong). These growths are referred to as lesions. During the menstrual cycle, estrogen levels rise and can cause endometriosis lesions to grow. Then, during a period, the lesions can break down and shred, causing pain throughout the month.

13. One way to manage common symptoms of endometriosis is to reduce the amount of estrogen the body produces. ORILISSA® inhibits endogenous GnRH signaling by binding competitive to GnRH receptors in the pituitary gland. ORILISSA® dials down estrogen, which can help manage endometriosis pain.

14. ORILISSA® was approved by the FDA on July 23, 2019, pursuant to NDA No. 210450. There are 2 different FDA approved dosage forms of ORILISSA®: 150 mg (administered orally once a day for management of moderate to severe pain associated with endometriosis) or 200 mg (administered orally twice a day for management of moderate to severe pain associated with endometriosis).

15. ORILISSA® is marketed and sold in the United States by AbbVie.

16. The '927, '211, '983, '572, '351, and '551 patents are listed in the Orange Book for ORILISSA®.

THE PARTIES

17. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is the assignee and owner of the '572, '351, and '551 patents. AbbVie Inc. holds NDA No. 210450 for ORILISSA®. AbbVie Inc. is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including endometriosis.

18. Plaintiff AbbVie Ltd. is a company organized and existing under the laws of Bermuda, with a registered address at Thistle House, 4 Burnaby Street, Hamilton HM 11,

Bermuda. AbbVie Ltd. is an indirect, wholly-owned subsidiary of AbbVie Inc. AbbVie Ltd. is the exclusive licensee of the '927, '211, and '983 patents from Plaintiff Neurocrine.

19. Plaintiff Neurocrine is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130. Neurocrine is the assignee and owner of the '927, '211, and '983 patents. Neurocrine is engaged in the business of researching, developing, and bringing to market innovative pharmaceutical products for the treatment of neurological, endocrine, and psychiatric disorders.

20. AbbVie (along with its predecessor companies) and Neurocrine developed ORILISSA®. AbbVie markets, distributes, and sells therapeutic drug products, including ORILISSA®, in this judicial district and throughout the United States.

21. On information and belief, Alkem is a company organized and existing under the laws of India, with a principal place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai MH 400013 India.

22. On information and belief, Alkem is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

23. On information and belief, Alkem caused Alkem's ANDA to be submitted to FDA and seeks FDA approval of Alkem's ANDA.

24. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of Alkem's ANDA, Alkem will directly or indirectly distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Alkem's ANDA throughout the United States, including the State of Delaware.

25. On information and belief, Hetero Labs is a company organized and existing under the laws of India, with a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

26. On information and belief, Hetero Unit-V is a corporation organized and existing under the laws of India, with its principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

27. On information and belief, Hetero Unit-V is a division of Hetero Labs.

28. On information and belief, Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

29. On information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Labs and Hetero Unit-V.

30. On information and belief, Hetero USA is a subsidiary of Hetero Labs.

31. On information and belief, each of Hetero Labs, Hetero Unit-V, and Hetero USA is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

32. On information and belief, the acts of Hetero USA complained of herein were done with the cooperation, participation, and assistance of Hetero Labs and Hetero Unit-V.

33. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA caused Hetero's ANDA to be submitted to FDA and seeks FDA approval of Hetero's ANDA.

34. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Hetero's ANDA, Hetero Labs, Hetero Unit-V, and

Hetero USA will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Hetero's ANDA throughout the United States, including the State of Delaware.

35. On information and belief, Lupin Limited is a company organized and existing under the laws of India, with a principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 005, India.

36. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware, with a principal place of business at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

37. On information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Limited.

38. On information and belief, each of Lupin Limited and Lupin Pharmaceuticals is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

39. On information and belief, the acts of Lupin Limited complained of herein were done with the cooperation, participation, and assistance of Lupin Pharmaceuticals.

40. On information and belief, Lupin Limited and Lupin Pharmaceuticals caused Lupin's ANDA to be submitted to FDA and seek FDA approval of Lupin's ANDA.

41. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Lupin's ANDA, Lupin Limited and Lupin Pharmaceuticals will act in concert to distribute and sell the proposed generic elagolix sodium oral

tablet (eq. 150 mg base and eq. 200 mg base) products described in Lupin's ANDA throughout the United States, including the State of Delaware.

42. On information and belief, MSN Laboratories is a company organized and existing under the laws of India, with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 500018 Telangana, India.

43. On information and belief, MSN Life Sciences is a corporation organized and existing under the laws of India, with a principal place of business at Sy No – 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) – 502313, Telangana, India.

44. On information and belief, MSN Life Sciences is a wholly-owned subsidiary of MSN Laboratories.

45. On information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

46. On information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

47. On information and belief, each of MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

48. On information and belief, the acts of MSN Laboratories complained of herein were done with the cooperation, participation, and assistance of MSN Life Sciences and MSN Pharmaceuticals.

49. On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals caused Hetero's ANDA to be submitted to FDA and seek FDA approval of MSN's ANDA.

50. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of MSN's ANDA, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in MSN's ANDA throughout the United States, including the State of Delaware.

51. On information and belief, Prinston Pharmaceutical is a corporation organized and existing under the laws of Delaware, with a principal place of business at 700 Atrium Dr., Somerset, New Jersey 08873.

52. On information and belief, Zhejiang Huahai is a corporation organized and existing under the laws of the People's Republic of China, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

53. On information and belief, Prinston Pharmaceutical is a wholly-owned subsidiary of Zhejiang Huahai.

54. On information and belief, Solco Healthcare is a company organized and existing under the laws of Delaware, with its principal place of business at 700 Atrium Dr., Suite A, Somerset, New Jersey 08873.

55. On information and belief, Solco Healthcare is a wholly-owned subsidiary of Prinston Pharmaceutical.

56. On information and belief, each of Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare is in the business of, *inter alia*, manufacturing, marketing, and selling generic

copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

57. On information and belief, the acts of Prinston Pharmaceutical complained of herein were done with the cooperation, participation, and assistance of Zhejiang Huahai and Solco Healthcare.

58. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare caused Prinston's ANDA to be submitted to FDA and seek FDA approval of Prinston's ANDA.

59. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Prinston's ANDA, Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Prinston's ANDA throughout the United States, including the State of Delaware.

60. On information and belief, Sandoz Inc. is a company organized and existing under the laws of Delaware, with a principal place of business at 100 College Rd. West, Princeton, New Jersey 08540.

61. On information and belief, Sandoz Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

62. On information and belief, Sandoz caused Sandoz's ANDA to be submitted to FDA and seeks FDA approval of Sandoz's ANDA.

63. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of Sandoz's ANDA, Sandoz Inc. will directly or

indirectly, distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Sandoz's ANDA throughout the United States, including the State of Delaware.

64. On information and belief, Sun is a company organized and existing under the laws of India, with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

65. On information and belief, Sun is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

66. On information and belief, Sun caused Sun's ANDA to be submitted to FDA and seeks FDA approval of Sun's ANDA.

67. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of Sun's ANDA, Sun will, directly or indirectly, distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Sun's ANDA throughout the United States, including the State of Delaware.

68. On information and belief, Teva Pharmaceuticals is a company organized and existing under the laws of Delaware, with a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

69. On information and belief, Teva Industries is a corporation organized and existing under the laws of Israel, with a principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel.

70. On information and belief, Teva Pharmaceuticals is a wholly-owned subsidiary of Teva Industries.

71. On information and belief, each of Teva Pharmaceuticals and Teva Industries is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

72. On information and belief, the acts of Teva Pharmaceuticals complained of herein were done with the cooperation, participation, and assistance of Teva Industries.

73. On information and belief, Teva Pharmaceuticals and Teva Industries caused Teva's ANDA to be submitted to FDA and seek FDA approval of Teva's ANDA.

74. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Teva's ANDA, Teva Pharmaceuticals and Teva Industries will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Teva's ANDA throughout the United States, including the State of Delaware.

75. On information and belief, Zenara Pharma is a company organized and existing under the laws of India, with a principal place of business at Plot No. 83/B, 84 & 87-96, Phase III, IDA Cherlapally, Hyderabad 500051, India.

76. On information and belief, Biophore is a corporation organized and existing under the laws of India, with a principal place of business at Plot No. 92, 1-98/2/92, Kavuri Hills, Phase II, Jubilee Hills, Hyderabad, 500033, India.

77. On information and belief, Zenara Pharma is a wholly-owned subsidiary of Biophore.

78. On information and belief, each of Zenara Pharma and Biophore is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

79. On information and belief, the acts of Zenara Pharma complained of herein were done with the cooperation, participation, and assistance of Biophore.

80. On information and belief, Zenara Pharma and Biophore caused Zenara's ANDA to be submitted to FDA and seek FDA approval of Zenara's ANDA.

81. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Zenara's ANDA, Zenara Pharma and Biophore will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Zenara's ANDA throughout the United States, including the State of Delaware.

JURISDICTION AND VENUE

82. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

83. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271.

84. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

Alkem

85. This Court has personal jurisdiction over Defendant Alkem because, on information and belief, Alkem, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Alkem's Generic Product in the State of Delaware upon approval of ANDA No. 217668.

86. On information and belief, Alkem purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either by itself or through its subsidiaries, agents, and/or alter egos, throughout the United States, including in this judicial district.

87. On information and belief, Alkem, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Alkem's website states: "Being the focal point of our international operations, we manufacture and supply a wide-range of generics and branded formulations in the United States. Our primary subsidiary, Ascend is ranked amongst the fastest growing companies in terms of generic drugs sales." (https://www.alkemlabs.com/us.php, accessed on Oct. 17, 2021). Alkem's website further states: "Our commitment to research has led us to cumulatively file over 144 ANDAs with the US FDA. Our products are available at major pharmacy chains, wholesalers, managed care companies, distributors and pharmaceutical retailers." *Id.* On information and belief, Alkem derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

88. This Court also has personal jurisdiction over Alkem because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Alkem satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work

or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

89. This Court also has personal jurisdiction over Alkem by virtue of the fact that, *inter alia*, Alkem has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

90. On information and belief, Alkem is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for ANDA No. 217668 for the commercial manufacture, use, and/or sale of Alkem's Generic Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Alkem has purposely availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district.

91. On information and belief, Alkem has been, and continues to be, responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 217668 with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") regarding the '572, '351, and '551 patents. On information and belief, and as indicated by a letter dated September 23, 2022, sent by Alkem to AbbVie Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), Alkem prepared and filed its ANDA with the intention of seeking to market Alkem's Generic Product nationwide, including within this judicial district.

92. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217668, Alkem will import, market, distribute, offer for sale, and/or sell Alkem's Generic Product described in ANDA No. 217668 throughout the United States, including in Delaware, either by itself or through its subsidiaries, agents, and/or alter egos, and will derive substantial revenue from the use or consumption of Alkem's Generic ANDA Product in the state of Delaware.

93. On information and belief, if ANDA No. 217668 is approved, Alkem's Generic ANDA Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

94. If ANDA No. 217668 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Alkem's Generic Product, including in Delaware.

95. This Court also has personal jurisdiction over Alkem because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Defendant Alkem has been sued multiple times in this District without challenging personal jurisdiction and Alkem has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *ZS Pharma, Inc. v. Alkem Labs. Ltd.*, C.A. No. 22-1096-GBW; *Anacor Pharms., Inc. v. Alkem Labs. Ltd.*, C.A. No. 21-1348-CFC; *Novartis Pharms. Corp. v. Alkem Labs. Ltd.*, C.A. No. 21-1330-LPS; *Allergan USA, Inc. v. Alkem Labs. Ltd.*, C.A. No. 21-1061-RGA; *Azurity Pharms., Inc. v. Alkem Labs. Ltd.*, C.A. No. 20-1094-MSG.

96. Alternatively, this Court has personal jurisdiction over Alkem pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state,

because Alkem is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Alkem has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

97. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alkem.

98. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), at least because Defendant Alkem is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction, including this judicial district.

Hetero

99. This Court has personal jurisdiction over Defendants Hetero Labs, Hetero Unit-V, and Hetero USA because, on information and belief, each of Hetero Labs, Hetero Unit-V, and Hetero USA, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Hetero's Generic Product in the State of Delaware upon approval of ANDA No. 217690.

100. This Court has personal jurisdiction over Hetero Labs. On information and belief, Hetero Labs "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate

Chemicals & Finished Dosages." (https://www.indiamart.com/heterolabs-limited/aboutus.html, accessed Oct. 17, 2022). On information and belief, Hetero Labs directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Labs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

101. This Court has personal jurisdiction over Hetero Unit-V. On information and belief, Hetero Unit-V is the drug manufacturing facility for Hetero Labs and manufactures Hetero's generic products. (*See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017, FDA Warning Letter, accessed Oct. 17, 2022). On information and belief, Hetero Unit-V directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

102. This Court has personal jurisdiction over Hetero USA because, *inter alia*, on information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware.

103. On information and belief, Hetero USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, W/K Incorporating Services, Inc., located at 3500 South DuPont Highway, Dover, Delaware 19901.

104. On information and belief, Hetero USA "is the sales and marketing arm of Hetero's Active Pharmaceutical Ingredients (API) and Custom Pharmaceutical Services (CPS) business in USA." (https://www.hetero.com/presence, accessed Oct. 17, 2022). On information and belief, Hetero USA directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

105. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

106. On information and belief, the acts of Hetero complained of herein were done with the cooperation, participation, and assistance of Hetero Labs, Hetero Unit-V, and Hetero USA.

107. This Court also has personal jurisdiction over Hetero Labs, Hetero Unit-V, and Hetero USA because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Hetero satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from

services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

108. This Court also has personal jurisdiction over Hetero Labs, Hetero Unit-V, and Hetero USA by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

109. On information and belief, the effort to seek approval for ANDA No. 217690 and to manufacture, import, market, and/or sell Hetero's Generic Product upon approval has been a cooperative and joint enterprise and venture between Hetero Labs, Hetero Unit-V, and Hetero USA.

110. On information and belief, Hetero Labs is the holder of FDA Drug Master File No. 37037 for elagolix sodium.

111. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217690 and in commercializing Hetero's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217690 upon approval. Through at least these activities, Hetero Labs, Hetero Unit-V, and Hetero USA have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

112. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have been, and continue to be the joint and prime actors responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 217690 with Paragraph IV certifications regarding the '927, '983, '572, '351, and '551 patents. On information and belief, and as indicated by a letter

dated September 12, 2022, sent by Hetero to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), "Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, a division of Hetero Labs Limited- (individually and/or collectively "Hetero")" prepared and filed its ANDA with the intention of seeking to market Hetero's Generic Product nationwide, including within this judicial district.

113. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217690, Hetero will act in concert to import, market, distribute, offer for sale, and/or sell Hetero's Generic Product described in ANDA No. 217690 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Hetero's Generic Product in the state of Delaware.

114. On information and belief, if ANDA No. 217690 is approved, Hetero's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

115. If ANDA No. 217690 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Hetero's Generic Product, including in Delaware.

116. This Court also has personal jurisdiction over Hetero because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Hetero has been sued multiple times in this District without challenging personal jurisdiction and Hetero has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Duchesnay, Inc. v. Hetero Labs. Ltd.*, C.A. No. 21-1130-LPS; *Novartis Pharms. Corp. v. Dr. Reddy's Labs., Inc.*, C.A. No. 19-2053-LPS; *Genentech, Inc. v. Hetero Labs*

Ltd., C.A. No. 19-178-RGA; *Biogen Int'l GmbH v. Amneal Pharms. LLC*, C.A. No. 17-823-LPS; *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, C.A. No. 18-1043-LPS.

117. Alternatively, this Court has personal jurisdiction over Hetero Labs pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Hetero Labs is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Hetero Labs has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

118. This Court also has personal jurisdiction over Hetero Unit-V pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Hetero Unit-V is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Hetero Unit-V has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

119. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero.

120. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero USA is incorporated in the State of Delaware.

121. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Labs is incorporated in India and may be sued in any judicial district in the United States.

122. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Unit-V is a division of Hetero Labs, which is incorporated in India and may be sued in any judicial district in the United States.

Lupin

123. This Court has personal jurisdiction over Defendants Lupin Limited and Lupin Pharmaceuticals because, on information and belief, each of Lupin Limited and Lupin Pharmaceuticals, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Lupin's Generic Product in the State of Delaware upon approval of ANDA No. 217712.

124. This Court has personal jurisdiction over Lupin Limited. On information and belief, Lupin Limited directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Lupin Limited's 2021-2022 Integrated report states that "Lupin continues to be the 3rd largest pharmaceutical player in both the U.S. generic market and U.S. total market by prescriptions." (https://www.lupin.com/wp-content/uploads/2022/07/integrated-report-consolidated.pdf, pg. 12, accessed Oct. 19, 2022). On information and belief, Lupin Limited purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

125. This Court has personal jurisdiction over Lupin Pharmaceuticals because, *inter alia,* on information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware.

126. On information and belief, Lupin Pharmaceuticals maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, The Corporation Trust Company, located at 1209 Orange St., Wilmington, Delaware, 19801.

127. On information and belief, Lupin Pharmaceuticals directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Lupin Pharmaceutical's website states: "Lupin's presence in the United States is comprised of a diverse workforce encompassing manufacturing, research and development, and commercial divisions for generics, complex generics, biosimilars and branded pharmaceuticals." (https://www.lupin.com/US/about-us/, accessed Oct. 19, 2022). Lupin Pharmaceutical's website further states: "Lupin's generic and specialty presence in the United States includes five physical office locations on the East Coast as well as a national salesforce operating throughout the country." (https://www.lupin.com/US/corporate-overview, accessed Oct. 19, 2022). On information and belief, Lupin Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

128. On information and belief, Lupin Limited and Lupin Pharmaceuticals, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Lupin Limited and Lupin Pharmaceuticals, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

129. On information and belief, the acts of Lupin complained of herein were done with the cooperation, participation, and assistance of Lupin Limited and Lupin Pharmaceuticals.

130. This Court also has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Lupin satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

131. This Court also has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

132. On information and belief, the effort to seek approval for ANDA No. 217712 and to manufacture, import, market, and/or sell Lupin's Generic Product upon approval has been a cooperative and joint enterprise and venture between Lupin Limited and Lupin Pharmaceuticals.

133. On information and belief, Lupin Limited is the holder of FDA Drug Master File No. 36669 for elagolix sodium.

134. On information and belief, Lupin Limited and Lupin Pharmaceuticals have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217712 and in commercializing Lupin's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217712 upon approval. Through at least these activities, Lupin Limited and Lupin Pharmaceuticals have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

135. On information and belief, Lupin Limited and Lupin Pharmaceuticals have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217712 with Paragraph IV certifications regarding the '927, '983, '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 16, 2022, sent by Lupin to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Lupin prepared and filed its ANDA with the intention of seeking to market Lupin's Generic Product nationwide, including within this judicial district.

136. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217712, Lupin will act in concert to market, distribute, and sell Lupin's Generic Product described in ANDA No. 217712 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Lupin's Generic Product in the state of Delaware.

137. On information and belief, if ANDA No. 217712 is approved, Lupin's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within

Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

138. If ANDA No. 217712 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Lupin's Generic Product, including in Delaware.

139. This Court also has personal jurisdiction over Lupin because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Lupin has been sued multiple times in this District without challenging personal jurisdiction and Lupin has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Neurocrine Biosciences, Inc. v. Lupin Ltd.*, C.A. No. 22-1061-MN; *Boehringer Ingelheim Pharms., Inc. v. Lupin Ltd.*, C.A. No. 21-1486-CFC; *Genentech, Inc. v. Lupin Ltd.*, C.A. No. 19-109-RGA; *Bayer Intell. Prop. GmbH v. Lupin Ltd.*, C.A. No. 17-1047-RGA; *ViiV Healthcare Co. v. Lupin Ltd.*, C.A. No. 17-1576-VAC-CJB.

140. Alternatively, this Court has personal jurisdiction over Lupin Limited pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Lupin Limited is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Lupin Limited has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

141. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Lupin.

142. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Lupin Pharmaceuticals is incorporated in the State of Delaware.

143. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Lupin Limited is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

MSN

144. This Court has personal jurisdiction over Defendants MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals because, on information and belief, each of MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell MSN's Generic Product in the State of Delaware upon approval of ANDA No. 217716.

145. On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals represent they are part of a single organization, the "MSN Group of Companies." (*See* https://www.msnlabs.com/who-we-are.html, accessed Oct. 19, 2022). For example, MSN's website states that "MSN Group is the fastest growing research-based pharmaceutical company based out of India." *Id.* MSN's website also states MSN Pharmaceuticals "is a fully owned subsidiary of the MSN group of companies." (https://www.msnlabs.com/msn-usa.html, accessed Oct. 19, 2022).

146. On information and belief, the acts of MSN complained of herein were done with the cooperation, participation, and assistance of MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals.

147. This Court has personal jurisdiction over MSN Pharmaceuticals because, *inter alia*, on information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware.

148. MSN Pharmaceuticals' website states that it is a "Specialized Pharmaceutical Generic development and manufacturing facility based out of Piscataway, New Jersey." (https://www.msnpi.com/, accessed Oct. 19, 2022).

149. On information and belief, MSN Pharmaceuticals maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, United States Corporation Agents, Inc., located at 221 N. Broad St., Suite 3A, Middletown, Delaware, 19709.

150. On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals each directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. MSN's company profile states: "The organization presently has 21 state-of-the-art manufacturing & R&D facilities (14 API, 6 finished dosages & one integrated R&D facility) established across India & USA." (MSN Company Profile available at https://www.msnlabs.com/downloads.html, accessed Oct. 19, 2022). On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals each has purposely conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of MSN's generic products.

151. On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. MSN's company profile states: "From 22 Million USD in 2005 to achieving over 670 Million USD turnover in FY 2021-22 and counting,

we continue to expand our growth and global footprint by creating innovative solutions for tomorrow's healthcare requirements." (MSN Company Profile available at https://www.msnlabs.com/downloads.html, accessed Oct. 19, 2022). On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals each derives substantial revenue from the sale of its generic products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

152. This Court also has personal jurisdiction over MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, MSN satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

153. This Court also has personal jurisdiction over MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

154. On information and belief, the effort to seek approval for ANDA No. 217716 and to manufacture, import, market, and/or sell MSN's Generic Product upon approval has been a

cooperative and joint enterprise and venture between MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals.

155. On information and belief, MSN Life Sciences is the holder of FDA Drug Master File No. 35701 for elagolix sodium.

156. On information and belief, between MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217716 and in commercializing MSN's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217716 upon approval. Through at least these activities, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

157. On information and belief, MSN Laboratories, MSN Life Sciences, and MSN Pharmaceuticals have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217716 with Paragraph IV certifications regarding the '927, '983, '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 27, 2022, sent by MSN to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), MSN prepared and filed its ANDA with the intention of seeking to market MSN's Generic Product nationwide, including within this judicial district.

158. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217716, MSN will act in concert to market, distribute, and sell MSN's Generic Product described in ANDA No. 217716 throughout

the United States, including in Delaware and will derive substantial revenue from the use or consumption of MSN's Generic Product in the state of Delaware.

159. On information and belief, if ANDA No. 217716 is approved, MSN's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

160. If ANDA No. 217716 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of MSN's Generic Product, including in Delaware.

161. This Court also has personal jurisdiction over MSN because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, MSN has been sued multiple times in this District without challenging personal jurisdiction and MSN has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Acerta Pharma B.V. v. MSN Pharms., Inc.*, C.A. No. 22-163-RGA; *Otsuka Pharms. Co. v. MSN Labs. Priv. Ltd.*, C.A. No. 20-1428-LPS; *Otsuka Pharm. Co. v. MSN Labs. Pvt. Ltd.*, C.A. No. 19-2009-LPS; *Allergan USA, Inc. v Aurobindo Pharma Ltd.*, C.A. No. 19-1727-RGA.

162. Alternatively, this Court has personal jurisdiction over MSN Laboratories pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because MSN Laboratories is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, MSN Laboratories has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or

distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

163. This Court also has personal jurisdiction over MSN Life Sciences pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because MSN Life Sciences is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, MSN Life Sciences has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

164. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN.

165. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because MSN Pharmaceuticals is incorporated in the State of Delaware.

166. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because MSN Laboratories and MSN Life Sciences are incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

Prinston

167. This Court has personal jurisdiction over Defendants Prinston Pharmaceutical, Zhejiang Huahai, and Solco because, on information and belief, each of Prinston Pharmaceutical, Zhejiang Huahai, and Solco, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of

doing business in the State of Delaware, and intends to sell Prinston's Generic Product in the State of Delaware upon approval of ANDA No. 217296.

168. This Court has personal jurisdiction over Prinston Pharmaceutical because, *inter alia*, Prinston Pharmaceutical is a corporation organized and existing under the laws of the State of Delaware.

169. On information and belief, Prinston Pharmaceutical maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, Delaware 19805.

170. On information and belief, Prinston Pharmaceutical directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Prinston Pharmaceutical's website states: "With more than 75 products under development or filed with regulatory agency in the US, Prinston will continue to build on its portfolio over the coming years." (http://www.prinstonpharm.com/, accessed Oct. 19, 2022). On information and belief, Prinston Pharmaceutical purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Prinston's generic products.

171. This Court has personal jurisdiction over Solco because, *inter alia*, Solco is a company organized and existing under the laws of the State of Delaware.

172. On information and belief, Solco maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, Delaware 19805.

173. On information and belief, Solco directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs

throughout the United States and in this judicial district. Prinston's website states: "Prinston markets its products through Solco Healthcare, wholly owned subsidiary, to retail pharmacies, wholesalers, distributors and group purchasing organizations." *Id.* On information and belief, Solco purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Solco's generic products.

174. This Court has personal jurisdiction over Zhejiang Huahai. On information and belief, Zhejiang Huahai directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Zhejiang Huahai's website states: "Huahai Pharmaceutical is the first Chinese pharmaceutical company that passed the US FDA certification for finished pharmaceutical products, obtained the ANDA approval for product developed by itself, and materialized the large-scale sales of finished dosages in the United States." (https://en.huahaipharm.com/qyjj/index.aspx, accessed Oct. 19, 2022). On information and belief, Zhejiang Huahai purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zhejiang Huahai's generic products.

175. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

176. On information and belief, the acts of Prinston complained of herein were done with the cooperation, participation, and assistance of Prinston Pharmaceutical, Zhejiang Huahai, and Solco.

177. This Court also has personal jurisdiction over Prinston Pharmaceutical, Zhejiang Huahai, and Solco because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Prinston satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

178. This Court also has personal jurisdiction over Prinston Pharmaceutical, Zhejiang Huahai, and Solco by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

179. On information and belief, the effort to seek approval for ANDA No. 217296 and to manufacture, import, market, and/or sell Prinston's Generic Product upon approval has been a cooperative and joint enterprise and venture between Prinston Pharmaceutical, Zhejiang Huahai, and Solco.

180. On information and belief, Zhejiang Huahai is the holder of FDA Drug Master File No. 36627 for elagolix sodium.

181. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217296 and in commercializing Prinston's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217296 upon approval. Through at least these activities, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

182. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217296.

183. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217296 with Paragraph IV certifications regarding the '927, '983, and '551 patents. On information and belief and as indicated by a letter dated September 13, 2022, sent by Prinston to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Prinston prepared and filed its ANDA with the intention of seeking to market Prinston's Generic Product nationwide, including within this judicial district.

184. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217296, Prinston will act in concert to market, distribute, and sell Prinston's Generic Product described in ANDA No. 217296 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Prinston's Generic Product in the state of Delaware.

185. On information and belief, if ANDA No. 217296 is approved, Prinston's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

186. If ANDA No. 217296 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Prinston's Generic Product, including in Delaware.

187. This Court also has personal jurisdiction over Prinston because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Prinston Pharmaceutical has been sued multiple times in this District without challenging personal jurisdiction and it has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Newron Pharms. S.p.A. v. Aurobindo Pharma Ltd.*, C.A. No. 21-843-RGA; *Otsuka Pharma. Co. v. Prinston Pharm. Inc.*, C.A. No. 20-1502-LPS; *Novartis Pharms. Corp. v. Apotex, Inc.*, C.A. No. 20-133-LPS; *Boehringer Ingelheim Pharms., Inc. v. Prinston Pharm. Inc.*, C.A. No. 19-1499-UNA; *H. Lundbeck A/S et al v. Prinston Pharm. Inc.*, 18-148-LPS.

188. Alternatively, this Court has personal jurisdiction over Zhejiang Huahai pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Zhejiang Huahai is a foreign entity organized under the laws of China, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Zhejiang Huahai has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or

distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

189. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Prinston.

190. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Prinston Pharmaceutical is incorporated in the State of Delaware.

191. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Solco is incorporated in the State of Delaware.

192. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zhejiang Huahai, is incorporated in China and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

Sandoz

193. This Court has personal jurisdiction over Defendant Sandoz because, on information and belief, Sandoz, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Sandoz's Generic Product in the State of Delaware upon approval of ANDA No. 217551.

194. This Court has personal jurisdiction over Sandoz Inc. because, *inter alia*, Sandoz Inc. is organized and existing under the laws of the State of Delaware.

195. On information and belief, Sandoz Inc. maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, Delaware 19808.

196. On information and belief, Sandoz purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either by itself or through its subsidiaries, agents, and/or alter egos, throughout the United States, including in this judicial district.

197. On information and belief, Sandoz either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Sandoz's website states: "Our global portfolio comprises approximately 1000 molecules, covering all a wide range of major therapeutic areas, which accounted for 2020 sales of USD 9.6 billion." (https://www.us.sandoz.com/our-work/what-we-do, accessed on Oct. 19, 2021). On information and belief, Sandoz derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

198. This Court also has personal jurisdiction over Sandoz because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Sandoz satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

199. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, Sandoz has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

200. On information and belief, is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for ANDA No. 217551 for the commercial manufacture, use, and/or sale of Sandoz's Generic Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Sandoz has purposely availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district.

201. On information and belief, Sandoz has been, and continues to be responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 217551 with Paragraph IV certifications regarding the '927, '211, '983, '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 29, 2022, sent by Sandoz to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Sandoz prepared and filed its ANDA with the intention of seeking to market Sandoz's Generic Product nationwide, including within this judicial district.

202. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217551, Sandoz will market, distribute, and sell Sandoz's Generic Product described in ANDA No. 217551 throughout the United States, including in Delaware, either by itself or through its subsidiaries, agents, and/or alter egos, and will derive substantial revenue from the use or consumption of Sandoz's Generic Product in the state of Delaware.

203. On information and belief, if ANDA No. 217551 is approved, Sandoz's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

204. If ANDA No. 217551 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Sandoz's Generic Product, including in Delaware.

205. This Court also has personal jurisdiction over Sandoz because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Sandoz has been sued multiple times in this District without challenging personal jurisdiction and Sandoz has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *ZS Pharma, Inc.*, C.A. No. 22-1101-GBW; *Acerta Pharma B.V. v. Sandoz Inc.*, C.A. No. 22-164-RGA; *Otsuka Pharma. Co., Ltd. v. Sandoz Inc.*, C.A. No. 21-580-LPS; *Biogen Int'l GmbH v. Sandoz, Inc.*, C.A. No. 17-874-LPS; *Bristol-Myers Squibb Co. v. Sandoz, Inc.*, C.A. No. 17-407-LPS.

206. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sandoz.

207. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Sandoz Inc. is incorporated in the State of Delaware.

Sun

208. This Court has personal jurisdiction over Defendant Sun because, on information and belief, Sun, *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

affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Sun's Generic Product in the State of Delaware upon approval of ANDA No. 215804.

209. On information and belief, Sun purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either by itself or through its subsidiaries, agents, and/or alter egos, throughout the United States, including in this judicial district.

210. On information and belief, Sun, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Sun's website states: "Sun Pharmaceutical Industries Ltd. (Sun Pharma) is the fourth largest specialty generic pharmaceutical company in the world with global revenues of over US$ 4.5 billion. Supported by more than 40 manufacturing facilities, we provide high-quality, affordable medicines, trusted by healthcare professionals and patients, to more than 100 countries across the globe." (https://sunpharma.com/about-us/, accessed on Oct. 19, 2021). Sun's website further states: "Being a vertically integrated company with a global presence, we have the flexibility to develop and manufacture products in the U.S. and other locations across the world." (https://sunpharma.com/usa/, accessed on Oct. 19, 2021). On information and belief, Sun derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

211. This Court also has personal jurisdiction over Sun because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Sun satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or

service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

212. This Court has personal jurisdiction over Sun by virtue of the fact that, *inter alia*, Sun has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

213. On information and belief, Sun is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for ANDA No. 215804 for the commercial manufacture, use, and/or sale of Sun's Generic Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Sun has purposely availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district.

214. On information and belief Sun has been, and continues to be responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 215804 with Paragraph IV certifications regarding the '927, '983, '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 16, 2022, sent by Sun to AbbVie Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), Sun prepared and filed its ANDA with the intention of seeking to market Sun's Generic Product nationwide, including within this judicial district.

215. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 215804, Sun will import, market, distribute, offer for sale, and/or sell Sun's Generic Product described in ANDA No. 215804 throughout the United States, including in Delaware, either by itself or through its subsidiaries, agents, and/or alter egos, and will derive substantial revenue from the use or consumption of Sun's Generic ANDA Product in the state of Delaware.

216. On information and belief, if ANDA No. 215804 is approved, Sun's Generic ANDA Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

217. If ANDA No. 215804 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Sun's Generic Product, including in Delaware.

218. This Court also has personal jurisdiction over Sun because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Defendant Sun has been sued multiple times in this District without challenging personal jurisdiction and Sun has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Novo Nordisk Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 22-896-CFC; *Boehringer Ingelheim Pharms., Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1573-CFC; *InfoRLife SA v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1740-CFC; *Galderma Labs. L.P. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1588-LPS; *Pfizer, Inc. v. Micro Labs USA, Inc.*, C.A. No. 17-158-LPS.

219. Alternatively, this Court has personal jurisdiction over Sun pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Sun is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Sun has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

220. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sun.

221. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Sun Pharmaceutical is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

Teva

222. This Court has personal jurisdiction over Defendants Teva Pharmaceuticals and Teva Industries because, on information and belief, each of Teva Pharmaceuticals and Teva Industries, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Teva's Generic Product in the State of Delaware upon approval of ANDA No. 217642.

223. This Court has personal jurisdiction over Teva Pharmaceuticals because, *inter alia*, Teva Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware.

224. On information and belief, Teva Pharmaceuticals maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, Delaware 19808.

225. On information and belief, Teva Pharmaceuticals directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Teva Pharmaceuticals' financial fact sheet states: "Teva is the leading generic drug company in the United States . . . ." (https://www.tevausa.com/globalassets/us/usa-files---global/teva-in-the-usa_fact-sheet_17.08.20.pdf, accessed Oct. 19, 2022). On information and belief, Teva Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

226. On information and belief, Teva Industries directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Teva Industries' SEC filing document states: "We are one of the leading generic pharmaceutical companies in the United States. We market over 550 generic prescription products in more than 1,600 dosage strengths, packaging sizes and forms, including oral solid dosage forms, injectable products, inhaled products, transdermal patches, liquids, ointments and creams. Most of our generic sales in the United States are made to retail drug chains, mail order distributors and wholesalers." (https://s24.q4cdn.com/720828402/files/doc_financials/2021/q4/2021-Form-10-K-

bannerless.pdf, pg. 3, accessed Oct. 19, 2022). On information and belief, Teva Industries purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

227. On information and belief, Teva Pharmaceuticals and Teva Industries, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Teva Pharmaceuticals and Teva Industries, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

228. On information and belief, the acts of Teva complained of herein were done with the cooperation, participation, and assistance of Teva Pharmaceuticals and Teva Industries.

229. This Court also has personal jurisdiction over Teva Pharmaceuticals and Teva Industries because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Teva satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

230. This Court also has personal jurisdiction over Teva Pharmaceuticals and Teva Industries by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced,

contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

231. On information and belief, the effort to seek approval for ANDA No. 217642 and to manufacture, import, market, and/or sell Teva's Generic Product upon approval has been a cooperative and joint enterprise and venture between Teva Pharmaceuticals and Teva Industries.

232. On information and belief, Teva Industries is the holder of FDA Drug Master File No. 36570 for elagolix sodium.

233. This Court also has personal jurisdiction over Teva because, *inter alia*, this action arises from activities of Teva directed toward Delaware.

234. On information and belief, Teva Pharmaceuticals and Teva Industries have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217642 and in commercializing Teva's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217642 upon approval. Through at least these activities, Teva Pharmaceuticals and Teva Industries have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

235. On information and belief, Teva Pharmaceuticals and Teva Industries have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217642.

236. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217642 with Paragraph IV certifications regarding the '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 12, 2022, sent by Teva to AbbVie Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), Teva

prepared and filed its ANDA with the intention of seeking to market Teva's Generic Product nationwide, including within this judicial district.

237. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217642, Teva will act in concert to market, distribute, and sell Teva's Generic Product described in ANDA No. 217642 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Teva's Generic Product in the state of Delaware.

238. On information and belief, if ANDA No. 217642 is approved, Teva's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

239. If ANDA No. 217642 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Teva's Generic Product, including in Delaware.

240. This Court also has personal jurisdiction over Teva because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Teva has been sued multiple times in this District without challenging personal jurisdiction and Teva has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Journey Med. Corp. v. Teva Pharms., Inc.*, C.A. No. 22-288-CFC; *Neurocrine Biosciences, Inc. v. Teva Pharms., Inc.*, C.A. No. 21-1043-MN; *Otsuka Pharm. Co. v. Teva Pharms., Inc.*, C.A. No. 22-513-RGA; *Anacor Pharms., Inc. v. Teva Pharms. Dev., Inc.*, C.A. No. 21-1353-CFC; *Valeant Pharms. Int'l v. Actavis Labs. FL, Inc.*, C.A. No. 18-1288-LPS; *Sun Pharma Global FZE v. Teva Pharms Indus. Ltd.*, C.A. No. 18-1552-RGA.

241. Alternatively, this Court has personal jurisdiction over Teva Industries pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Teva Industries is a foreign entity organized under the laws of Israel, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Teva Industries has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

242. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

243. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Pharmaceuticals is incorporated in the State of Delaware.

244. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Industries, is incorporated in Israel and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

Zenara

245. This Court has personal jurisdiction over Defendants Zenara Pharma and Biophore because, on information and belief, each of Zenara Pharma and Biophore, *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 affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Zenara's Generic Product in the State of Delaware upon approval of ANDA No. 217760.

246. This Court has personal jurisdiction over Zenara Pharma. Zenara Pharma's website states that Zenara Pharma is a "US FDA, EU and WHO-GMP approved Oral Solid and Liquid manufacturing Facility" with "More than 20 plus ANDA/ANDs under approval." (https://www.zenarapharma.com/, accessed Oct. 19, 2022). Zenara Pharma's website also states: "We are constantly strengthening our global supply chain with customers in key markets including United States . . . ." (https://www.zenarapharma.com/manufacturing.php, accessed Oct. 19, 2022). On information and belief, Zenara Pharma purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zenara's generic products.

247. This Court has personal jurisdiction over Biophore. Biophore's website states: "We have consistently been in the Top 10 US DMF filers with the US FDA over the past 5 years . . . ." (http://www.biophore.com/aboutus.php#p1, accessed Oct. 19, 2022). On information and belief, Biophore purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zenara's generic products.

248. On information and belief, Zenara Pharma and Biophore, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Zenara Pharma and Biophore, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

249. On information and belief, the acts of Zenara complained of herein were done with the cooperation, participation, and assistance of Zenara Pharma and Biophore.

250. This Court also has personal jurisdiction over Zenara Pharma and Biophore because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On

information and belief, Zenara satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

251. This Court also has personal jurisdiction over Zenara Pharma and Biophore by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs in this District.

252. On information and belief, the effort to seek approval for ANDA No. 217760 and to manufacture, import, market, and/or sell Zenara's Generic Product upon approval has been a cooperative and joint enterprise and venture between Zenara Pharma and Biophore.

253. On information and belief, Biphore is the holder of FDA Drug Master File No. 36646 for elagolix sodium.

254. On information and belief, Zenara Pharma and Biophore have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217760 and in commercializing Zenara's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217760 upon approval. Through at least these activities, Zenara Pharma and Biophore have purposely availed themselves

of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

255. On information and belief Zenara Pharma and Biophore have been, and continue to be the joint and prime actors responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 217760 with Paragraph IV certifications regarding the '572, '351, and '551 patents. On information and belief and as indicated by a letter dated September 28, 2022, sent by Zenara to AbbVie Inc. pursuant to 21 U.S.C. § 355(j)(2)(B), Zenara prepared and filed its ANDA with the intention of seeking to market Zenara's Generic Product nationwide, including within this judicial district.

256. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217760, Zenara will act in concert to import, market, distribute, offer for sale, and/or sell Zenara's Generic Product described in ANDA No. 217760 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Zenara's Generic Product in the state of Delaware.

257. On information and belief, if ANDA No. 217760 is approved, Zenara's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

258. If ANDA No. 217760 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Zenara's Generic Product, including in Delaware.

259. This Court also has personal jurisdiction over Zenara because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular,

Defendant Zenara has been sued multiple times in this District without challenging personal jurisdiction. *See, e.g.*, *Otsuka Pharm. Co. v. Zenara Pharma Priv. Ltd.*, C.A. No. 22-1269-LPS; *Merck Sharp & Dohme Corp. v. Zenara Pharma Priv. Ltd.*, C.A. No. 22-379-VAC; *Otsuka Pharm. Co. v. Zenara Pharma Priv. Ltd.*, C.A. No. 20-1599-UNA; *Otsuka Pharm. Co. v. Zenara Pharma Priv. Ltd.*, C.A. No. 19-1938-LPS; *Genzyme Corp. v. Zenara Pharma Priv. Ltd.*, C.A. No. 19-264-CFC.

260. Alternatively, this Court has personal jurisdiction over Zenara Pharma pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Zenara Pharma is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Zenara Pharma has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

261. This Court also has personal jurisdiction over Biophore pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Biophore is a foreign entity organized under the laws of India, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Biophore has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

262. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Zenara.

263. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Zenara Pharma is incorporated in India and may be sued in any judicial district in the United States.

264. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Biophore is incorporated in India and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

265. AbbVie Inc. is the holder of NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

266. The FDA approved NDA No. 210450 on July 23, 2018, for management of moderate to severe pain associated with endometriosis.

267. ORILISSA® Tablets are prescription drugs approved for the management of moderate to severe pain associated with endometriosis. Elagolix sodium is the active ingredient in the ORILISSA® Tablets.

The Asserted Patents

268. The '927 patent, titled "Gonadotropin-Releasing Hormone Receptor Antagonists and Methods Relating Thereto" was duly and legally issued by the United States Patent and Trademark Office on June 6, 2006. A true and correct copy of the '927 patent is attached as Exhibit A.

269. Neurocrine Biosciences, Inc. owns the rights to the '927 patent. AbbVie Ltd. is the exclusive licensee of the '927 patent. The '927 patent currently expires on September 10, 2024, exclusive of any patent term extension awarded.

270. Neurocrine filed an Application for Extension of Patent Term Under 35 U.S.C. § 156 for the '927 patent, requesting an extension under 35 U.S.C. § 156 of 1,826 days. Accordingly, the '927 patent will expire on September 10, 2029, if granted the 1,826 days of Patent Term Extension under 35 U.S.C. § 156.

271. The '927 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

272. The '211 patent, titled "Gonadotropin-Releasing Hormone Receptor Antagonists and Methods Relating Thereto" was duly and legally issued by the United States Patent and Trademark Office on February 13, 2007. A true and correct copy of the '211 patent is attached as Exhibit B.

273. Neurocrine Biosciences, Inc. owns the rights to the '211 patent. AbbVie Ltd. is the exclusive licensee of the '211 patent. The '211 patent will expire on July 6, 2024.

274. The '211 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

275. The '983 patent, titled "Gonadotropin-Releasing Hormone Receptor Antagonists and Methods Relating Thereto" was duly and legally issued by the United States Patent and Trademark Office on September 2, 2008. A true and correct copy of the '983 patent is attached as Exhibit C.

276. Neurocrine Biosciences, Inc. owns the rights to the '983 patent. AbbVie Ltd. is the exclusive licensee of the '983 patent. The '983 patent will expire on July 6, 2024, exclusive of any patent term extension awarded.

277. Neurocrine filed an Application for Extension of Patent Term Under 35 U.S.C. § 156 for the '983 patent, requesting an extension under 35 U.S.C. § 156 of 1,826 days. Accordingly, the '983 patent will expire on July 6, 2029, if granted the 1,826 days of Patent Term Extension under 35 U.S.C. § 156.

278. The '983 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

279. The '572 patent, titled "Methods of Administering Elagolix" was duly and legally issued by the United States Patent and Trademark Office on January 21, 2020. A true and correct copy of the '572 patent is attached as Exhibit D.

280. AbbVie Inc. owns the rights to the '572 patent. The '572 patent will expire on September 1, 2036.

281. The '572 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base)) Tablets .

282. The '351 patent, titled "Methods of Administering Elagolix" was duly and legally issued by the United States Patent and Trademark Office on June 16, 2020. A true and correct copy of the '351 patent is attached as Exhibit E.

283. AbbVie Inc. owns the rights to the '351 patent. The '351 patent will expire on September 1, 2036.

284. The ’351 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablet (eq. 150 mg base)) Tablets.

285. The ’551 patent, titled “Methods of Treating Heavy Menstrual Bleeding” was duly and legally issued by the United States Patent and Trademark Office on May 31, 2022. A true and correct copy of the ’551 patent is attached as Exhibit F.

286. AbbVie Inc. owns the rights to the ’551 patent. The ’244 patent will expire on March 14, 2034.

287. The ’551 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 200 mg base)) Tablets.

Alkem’s ANDA No. 217668

288. On information and belief, Alkem filed ANDA No. 217668 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs’ ORILISSA® (elagolix sodium) Tablets.

289. ANDA No. 217668 contains Paragraph IV certifications, alleging that the claims of the ’572, ’351, and ’551 patents are invalid, unenforceable, and/or would not be infringed by Alkem’s Generic Product.

290. AbbVie Inc. received a letter sent by Alkem, dated September 23, 2022, purporting to be a “Notification of Paragraph IV Certification” for ANDA No. 217668 (“Alkem’s Notice Letter”) pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Alkem’s Notice Letter notified AbbVie that Alkem had filed ANDA No. 217668,

seeking approval to market Alkem's Generic Product prior to the expiration of the '572, '351, and '551 patents.

291. Plaintiffs commenced this action within 45 days of receiving Alkem's September 23, 2022 Notice Letter.

292. On information and belief, following FDA approval of Alkem's ANDA No. 217668, Alkem will make, use, sell, or offer to sell Alkem's Generic Product throughout the United States, or import such generic products into the United States before the '572, '351, and '551 patents expire.

Hetero's ANDA No. 217690

293. On information and belief, Hetero filed ANDA No. 217690 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

294. ANDA No. 217690 contains Paragraph IV certifications, alleging that the claims of the '927, '983, '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Hetero's Generic Product.

295. Plaintiffs received a letter sent by Hetero, dated September 12, 2022, purporting to be a "Notification of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii)" for ANDA No. 217690 ("Hetero's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Hetero's Notice Letter notified Plaintiffs that Hetero had filed ANDA No. 217690, seeking approval to market Hetero's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents.

296. Plaintiffs commenced this action within 45 days of receiving Hetero's September 12, 2022 Notice Letter.

297. On information and belief, following FDA approval of Hetero's ANDA No. 217690, Hetero will make, use, sell, or offer to sell Hetero's Generic Product throughout the United States, or import such generic products into the United States before the '927, '983, '572, '351, and '551 patents expire.

Lupin's ANDA No. 217712

298. On information and belief, Lupin filed ANDA No. 217712 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

299. ANDA No. 217712 contains Paragraph IV certifications, alleging that the claims of the '927, '983, '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Lupin's Generic Product.

300. Plaintiffs received a letter sent by Lupin, dated September 16, 2022, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217712 ("Lupin's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Lupin's Notice Letter notified Plaintiffs that Lupin had filed ANDA No. 217712, seeking approval to market Lupin's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents.

301. Plaintiffs commenced this action within 45 days of receiving Lupin's September 16, 2022 Notice Letter.

302. On information and belief, following FDA approval of Lupin's ANDA No. 217712, Lupin will make, use, sell, or offer to sell Lupin's Generic Product throughout the United States, or import such generic products into the United States before the '927, '983, '572, '351, and '551 patents expire.

MSN's ANDA No. 217716

303. On information and belief, MSN filed ANDA No. 217716 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

304. ANDA No. 217716 contains Paragraph IV certifications, alleging that the claims of the '927, '983, '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by MSN's Generic Product.

305. Plaintiffs received a letter sent by MSN, dated September 27, 2022, purporting to be a "Notification of Certifications . . . Pursuant to § 505(j)(2)(B)(iv)" for ANDA No. 217716 ("MSN's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. MSN's Notice Letter notified Plaintiffs that MSN had filed ANDA No. 217716, seeking approval to market MSN's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents.

306. Plaintiffs commenced this action within 45 days of receiving MSN's September 27, 2022 Notice Letter.

307. On information and belief, following FDA approval of MSN's ANDA No. 217716, MSN will make, use, sell, or offer to sell MSN's Generic Product throughout the United States, or

import such generic products into the United States before the '927, '983, '572, '351, and '551 patents expire.

Prinston's ANDA No. 217296

308. On information and belief, Prinston filed ANDA No. 217296 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

309. ANDA No. 217296 contains Paragraph IV certifications, alleging that the claims of the '927, '983, and '551 patents are invalid, unenforceable, and/or would not be infringed by Prinston's Generic Product.

310. Plaintiffs received a letter sent by Prinston, dated September 13, 2022, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217296 ("Prinston's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Prinston's Notice Letter notified Plaintiffs that Prinston had filed ANDA No. 217296, seeking approval to market Prinston's Generic Product prior to the expiration of the '927, '983, and '551 patents.

311. Plaintiffs commenced this action within 45 days of receiving Prinston's September 13, 2022 Notice Letter.

312. On information and belief, following FDA approval of Prinston's ANDA No. 217296, Prinston will make, use, sell, or offer to sell Prinston's Generic Product throughout the United States, or import such generic products into the United States before the '927, '983, and '551 patents expire.

Sandoz's ANDA No. 217551

313. On information and belief, Sandoz filed ANDA No. 217551 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

314. ANDA No. 217551 contains Paragraph IV certifications, alleging that the claims of the '927, '211, '983, '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Sandoz's Generic Product.

315. Plaintiffs received a letter sent by Sandoz, dated September 29, 2022, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217551 ("Sandoz's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Sandoz's Notice Letter notified Plaintiffs that Sandoz had filed ANDA No. 217551, seeking approval to market Sandoz's Generic Product prior to the expiration of the '927, '211, '983, '572, '351, and '551 patents.

316. Plaintiffs commenced this action within 45 days of receiving Sandoz's September 29, 2022 Notice Letter.

317. On information and belief, following FDA approval of Sandoz's ANDA No. 217551, Sandoz will make, use, sell, or offer to sell Sandoz's Generic Product throughout the United States, or import such generic products into the United States before the '927, '211, '983, '572, '351, and '551 patents expire.

Sun's ANDA No. 215804

318. On information and belief, Sun filed ANDA No. 215804 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

319. ANDA No. 215804 contains Paragraph IV, alleging that the claims of the '927, '983, '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Sun's Generic Product.

320. AbbVie Inc. received a letter sent by Sun, dated September 16, 2022, purporting to be a "Notice of Certification Pursuant to Federal Food, Drug and Cosmetic Act" for ANDA No. 215804 ("Sun's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Sun's Notice Letter notified AbbVie that Sun had filed ANDA No. 215804, seeking approval to market Sun's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents.

321. Plaintiffs commenced this action within 45 days of receiving Sun's September 16, 2022 Notice Letter.

322. On information and belief, following FDA approval of Sun's ANDA No. 215804, Sun will make, use, sell, or offer to sell Sun's Generic Product throughout the United States, or import such generic products into the United States before the '927, '983, '572, '351, and '551 patents expire.

Teva's ANDA No. 217642

323. On information and belief, Teva filed ANDA No. 217642 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

324. ANDA No. 217642 contains Paragraph IV certifications, alleging that the claims of the '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Teva's Generic Product.

325. AbbVie Inc. received a letter sent by Teva, dated September 12, 2022, purporting to be a "Notice of ANDA No. 217642 . . . With Paragraph IV Certification" for ANDA No. 217642 ("Teva's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Teva's Notice Letter notified AbbVie that Teva had filed ANDA No. 217642, seeking approval to market Teva's Generic Product prior to the expiration of the '572, '351, and '551 patents.

326. Plaintiffs commenced this action within 45 days of receiving Teva's September 12, 2022 Notice Letter.

327. On information and belief, following FDA approval of Teva's ANDA No. 217642, Teva will make, use, sell, or offer to sell Teva's Generic Product throughout the United States, or import such generic products into the United States before the '572, '351, and '551 patents expire.

Zenara's ANDA No. 217760

328. On information and belief, Zenara filed ANDA No. 217760 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for

sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiffs' ORILISSA® (elagolix sodium) Tablets.

329. ANDA No. 217760 contains Paragraph IV certifications, alleging that the claims of the '572, '351, and '551 patents are invalid, unenforceable, and/or would not be infringed by Zenara's Generic Product.

330. AbbVie Inc. received a letter sent by Zenara, dated September 28, 2022, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217760 ("Zenara's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Zenara's Notice Letter notified AbbVie that Zenara had filed ANDA No. 217760, seeking approval to market Zenara's Generic Product prior to the expiration of the '572, '351, and '551 patents.

331. Plaintiffs commenced this action within 45 days of receiving Zenara's September 28, 2022 Notice Letter.

332. On information and belief, following FDA approval of Zenara's ANDA No. 217760, Zenara will make, use, sell, or offer to sell Zenara's Generic Product throughout the United States, or import such generic products into the United States before the '572, '351, and '551 patents expire.

COUNT I
INFRINGEMENT OF THE '572 PATENT BY ALKEM

333. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

334. On information and belief, Alkem filed Alkem's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem's Generic Product in the United States before the expiration of the '572 patent.

335. On information and belief, Alkem filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

336. On information and belief, in Alkem's ANDA, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

337. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Alkem's ANDA seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

338. After FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Alkem's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Alkem's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

339. On information and belief, Alkem knows, or should know, and intends that healthcare providers will prescribe and patients will take Alkem's Generic Product for which approval is sought in Alkem's ANDA, and therefore will infringe at least one claim in the '572 patent.

340. On information and belief, Alkem had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Alkem's Generic Product, knows or should

know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

341. On information and belief, Alkem is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Alkem's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

342. The offering to sell, sale, making, and/or importation of Alkem's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents. Alkem has knowledge and is aware of the '572 patent, as evidenced by Alkem's September 23, 2022 Notice Letter.

343. On information and belief, if Alkem's ANDA is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

344. On information and belief, Alkem's actions relating to Alkem's ANDA complained of herein were done by and for the benefit of Alkem.

345. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II
INFRINGEMENT OF THE '351 PATENT BY ALKEM

346. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

347. On information and belief, Alkem filed Alkem's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem's Generic Product in the United States before the expiration of the '351 patent.

348. On information and belief, Alkem filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

349. On information and belief, in Alkem's ANDA, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

350. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Alkem's ANDA seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

351. After FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Alkem's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Alkem's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

352. On information and belief, Alkem knows, or should know, and intends that healthcare providers will prescribe and patients will take Alkem's Generic Product for which approval is sought in Alkem's ANDA, and therefore will infringe at least one claim in the '351 patent.

353. On information and belief, Alkem had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Alkem's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

354. On information and belief, Alkem is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Alkem's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

355. The offering to sell, sale, making, and/or importation of Alkem's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Alkem has knowledge and is aware of the '351 patent, as evidenced by Alkem's September 23, 2022 Notice Letter.

356. On information and belief, if Alkem's ANDA is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

357. On information and belief, Alkem's actions relating to Alkem's ANDA complained of herein were done by and for the benefit of Alkem.

358. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT III
INFRINGEMENT OF THE '551 PATENT BY ALKEM

359. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

360. On information and belief, Alkem filed Alkem's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem's Generic Product in the United States before the expiration of the '551 patent.

361. On information and belief, Alkem filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

362. On information and belief, in Alkem's ANDA, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

363. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Alkem's ANDA seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

364. After FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Alkem's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Alkem's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

365. On information and belief, Alkem knows, or should know, and intends that healthcare providers will prescribe and patients will take Alkem's Generic Product for which approval is sought in Alkem's ANDA, and therefore will infringe at least one claim in the '551 patent.

366. On information and belief, Alkem had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Alkem's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

367. On information and belief, Alkem is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Alkem's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

368. The offering to sell, sale, making, and/or importation of Alkem's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Alkem has knowledge and is aware of the '551 patent, as evidenced by Alkem's September 23, 2022 Notice Letter.

369. On information and belief, if Alkem's ANDA is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

370. Alkem has had and continues to have knowledge that Alkem's Generic Product is especially adapted for a use that infringes the '551 patent.

371. On information and belief, Alkem has had and continues to have knowledge that there is no substantial non-infringing use for Alkem's Generic Product.

372. On information and belief, Alkem's actions relating to Alkem's ANDA complained of herein were done by and for the benefit of Alkem.

373. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IV
INFRINGEMENT OF THE '927 PATENT BY HETERO

374. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

375. On information and belief, Hetero filed Hetero's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '927 patent.

376. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

377. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

378. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

379. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

380. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '927 patent.

381. On information and belief, Hetero had knowledge of the '927 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

382. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

383. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '927 patent, as evidenced by Hetero's September 12, 2022 Notice Letter.

384. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

385. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '927 patent.

386. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

387. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

388. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT V
INFRINGEMENT OF THE '983 PATENT BY HETERO

389. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

390. On information and belief, Hetero filed Hetero's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '983 patent.

391. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

392. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

393. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before

the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

394. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

395. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '983 patent.

396. On information and belief, Hetero had knowledge of the '983 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

397. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

398. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally

or under the doctrine of equivalents. Hetero has knowledge and is aware of the '983 patent, as evidenced by Hetero's September 12, 2022 Notice Letter.

399. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

400. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '983 patent.

401. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

402. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

403. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VI
INFRINGEMENT OF THE '572 PATENT BY HETERO

404. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

405. On information and belief, Hetero filed Hetero's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '572 patent.

406. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

407. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

408. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

409. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

410. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '572 patent.

411. On information and belief, Hetero had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

412. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

413. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '572 patent, as evidenced by Hetero's September 12, 2022 Notice Letter.

414. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

415. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

416. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VII
INFRINGEMENT OF THE '351 PATENT BY HETERO

417. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

418. On information and belief, Hetero filed Hetero's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '351 patent.

419. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

420. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

421. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

422. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

423. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '351 patent.

424. On information and belief, Hetero had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

425. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

426. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '351 patent, as evidenced by Hetero's September 12, 2022 Notice Letter.

427. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

428. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

429. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VIII
INFRINGEMENT OF THE '551 PATENT BY HETERO

430. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

431. On information and belief, Hetero filed Hetero's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '551 patent.

432. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

433. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

434. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

435. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

436. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '551 patent.

437. On information and belief, Hetero had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

438. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

439. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '551 patent, as evidenced by Hetero's September 12, 2022 Notice Letter.

440. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

441. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '551 patent.

442. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

443. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

444. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IX
INFRINGEMENT OF THE '927 PATENT BY LUPIN

445. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

446. On information and belief, Lupin filed Lupin's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '927 patent.

447. On information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

448. On information and belief, in Lupin's ANDA, Lupin has represented to the FDA that Lupin's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

449. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Lupin's ANDA seeking approval for the commercial manufacture, use, or sale of Lupin's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

450. After FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

451. On information and belief, Lupin knows, or should know, and intends that healthcare providers will prescribe and patients will take Lupin's Generic Product for which approval is sought in Lupin's ANDA, and therefore will infringe at least one claim in the '927 patent.

452. On information and belief, Lupin had knowledge of the '927 patent and, by its promotional activities and proposed package insert for Lupin's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

453. On information and belief, Lupin is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Lupin's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

454. The offering to sell, sale, making, and/or importation of Lupin's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. Lupin has knowledge and is aware of the '927 patent, as evidenced by Lupin's September 16, 2022 Notice Letter.

455. On information and belief, if Lupin's ANDA is approved, Lupin intends to and will offer to sell, sell, and/or import in the United States Lupin's Generic Product.

456. Lupin has had and continues to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '927 patent.

457. On information and belief, Lupin has had and continues to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

458. On information and belief, Lupin's actions relating to Lupin's ANDA complained of herein were done by and for the benefit of Lupin.

459. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT X
INFRINGEMENT OF THE '983 PATENT BY LUPIN

460. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

461. On information and belief, Lupin filed Lupin's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '983 patent.

462. On information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

463. On information and belief, in Lupin's ANDA, Lupin has represented to the FDA that Lupin's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

464. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Lupin's ANDA seeking approval for the commercial manufacture, use, or sale of Lupin's Generic Product before the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

465. After FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

466. On information and belief, Lupin knows, or should know, and intends that healthcare providers will prescribe and patients will take Lupin's Generic Product for which approval is sought in Lupin's ANDA, and therefore will infringe at least one claim in the '983 patent.

467. On information and belief, Lupin had knowledge of the '983 patent and, by its promotional activities and proposed package insert for Lupin's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

468. On information and belief, Lupin is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Lupin's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

469. The offering to sell, sale, making, and/or importation of Lupin's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents. Lupin has knowledge and is aware of the '983 patent, as evidenced by Lupin's September 16, 2022 Notice Letter.

470. On information and belief, if Lupin's ANDA is approved, Lupin intends to and will offer to sell, sell, and/or import in the United States Lupin's Generic Product.

471. Lupin has had and continues to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '983 patent.

472. On information and belief, Lupin has had and continues to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

473. On information and belief, Lupin's actions relating to Lupin's ANDA complained of herein were done by and for the benefit of Lupin.

474. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XI
INFRINGEMENT OF THE '572 PATENT BY LUPIN

475. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

476. On information and belief, Lupin filed Lupin's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '572 patent.

477. On information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

478. On information and belief, in Lupin's ANDA, Lupin has represented to the FDA that Lupin's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

479. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Lupin's ANDA seeking approval for the commercial manufacture, use, or sale of Lupin's Generic Product before

the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

480. After FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

481. On information and belief, Lupin knows, or should know, and intends that healthcare providers will prescribe and patients will take Lupin's Generic Product for which approval is sought in Lupin's ANDA, and therefore will infringe at least one claim in the '572 patent.

482. On information and belief, Lupin had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Lupin's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

483. On information and belief, Lupin is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Lupin's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

484. The offering to sell, sale, making, and/or importation of Lupin's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally

or under the doctrine of equivalents. Lupin has knowledge and is aware of the '572 patent, as evidenced by Lupin's September 16, 2022 Notice Letter.

485. On information and belief, if Lupin's ANDA is approved, Lupin intends to and will offer to sell, sell, and/or import in the United States Lupin's Generic Product.

486. On information and belief, Lupin's actions relating to Lupin's ANDA complained of herein were done by and for the benefit of Lupin.

487. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XII
INFRINGEMENT OF THE '351 PATENT BY LUPIN

488. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

489. On information and belief, Lupin filed Lupin's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '351 patent.

490. On information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

491. On information and belief, in Lupin's ANDA, Lupin has represented to the FDA that Lupin's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

492. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Lupin's ANDA seeking approval for the commercial manufacture, use, or sale of Lupin's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

493. After FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

494. On information and belief, Lupin knows, or should know, and intends that healthcare providers will prescribe and patients will take Lupin's Generic Product for which approval is sought in Lupin's ANDA, and therefore will infringe at least one claim in the '351 patent.

495. On information and belief, Lupin had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Lupin's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

496. On information and belief, Lupin is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Lupin's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

497. The offering to sell, sale, making, and/or importation of Lupin's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Lupin has knowledge and is aware of the '351 patent, as evidenced by Lupin's September 16, 2022 Notice Letter.

498. On information and belief, if Lupin's ANDA is approved, Lupin intends to and will offer to sell, sell, and/or import in the United States Lupin's Generic Product.

499. On information and belief, Lupin's actions relating to Lupin's ANDA complained of herein were done by and for the benefit of Lupin.

500. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XIII
INFRINGEMENT OF THE '551 PATENT BY LUPIN

501. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

502. On information and belief, Lupin filed Lupin's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '551 patent.

503. On information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

504. On information and belief, in Lupin's ANDA, Lupin has represented to the FDA that Lupin's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

505. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Lupin's ANDA seeking approval for the commercial manufacture, use, or sale of Lupin's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

506. After FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

507. On information and belief, Lupin knows, or should know, and intends that healthcare providers will prescribe and patients will take Lupin's Generic Product for which approval is sought in Lupin's ANDA, and therefore will infringe at least one claim in the '551 patent.

508. On information and belief, Lupin had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Lupin's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

509. On information and belief, Lupin is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Lupin's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

510. The offering to sell, sale, making, and/or importation of Lupin's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Lupin has knowledge and is aware of the '551 patent, as evidenced by Lupin's September 16, 2022 Notice Letter.

511. On information and belief, if Lupin's ANDA is approved, Lupin intends to and will offer to sell, sell, and/or import in the United States Lupin's Generic Product.

512. Lupin has had and continues to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '551 patent.

513. On information and belief, Lupin has had and continues to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

514. On information and belief, Lupin's actions relating to Lupin's ANDA complained of herein were done by and for the benefit of Lupin.

515. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XIV
INFRINGEMENT OF THE '927 PATENT BY MSN

516. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

517. On information and belief, MSN filed MSN's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '927 patent.

518. On information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

519. On information and belief, in MSN's ANDA, MSN has represented to the FDA that MSN's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

520. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

521. After FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing MSN's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of MSN's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

522. On information and belief, MSN knows, or should know, and intends that healthcare providers will prescribe and patients will take MSN's Generic Product for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '927 patent.

523. On information and belief, MSN had knowledge of the '927 patent and, by its promotional activities and proposed package insert for MSN's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

524. On information and belief, MSN is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use MSN's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

525. The offering to sell, sale, making, and/or importation of MSN's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. MSN has knowledge and is aware of the '927 patent, as evidenced by MSN's September 27, 2022 Notice Letter.

526. On information and belief, if MSN's ANDA is approved, MSN intends to and will offer to sell, sell, and/or import in the United States MSN's Generic Product.

527. MSN has had and continues to have knowledge that MSN's Generic Product is especially adapted for a use that infringes the '927 patent.

528. On information and belief, MSN has had and continues to have knowledge that there is no substantial non-infringing use for MSN's Generic Product.

529. On information and belief, MSN's actions relating to MSN's ANDA complained of herein were done by and for the benefit of MSN.

530. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XV
INFRINGEMENT OF THE '983 PATENT BY MSN

531. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

532. On information and belief, MSN filed MSN's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '983 patent.

533. On information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

534. On information and belief, in MSN's ANDA, MSN has represented to the FDA that MSN's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

535. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's Generic Product before the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

536. After FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing MSN's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of MSN's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

537. On information and belief, MSN knows, or should know, and intends that healthcare providers will prescribe and patients will take MSN's Generic Product for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '983 patent.

538. On information and belief, MSN had knowledge of the '983 patent and, by its promotional activities and proposed package insert for MSN's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

539. On information and belief, MSN is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use MSN's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

540. The offering to sell, sale, making, and/or importation of MSN's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents. MSN has knowledge and is aware of the '983 patent, as evidenced by MSN's September 27, 2022 Notice Letter.

541. On information and belief, if MSN's ANDA is approved, MSN intends to and will offer to sell, sell, and/or import in the United States MSN's Generic Product.

542. MSN has had and continues to have knowledge that MSN's Generic Product is especially adapted for a use that infringes the '983 patent.

543. On information and belief, MSN has had and continues to have knowledge that there is no substantial non-infringing use for MSN's Generic Product.

544. On information and belief, MSN's actions relating to MSN's ANDA complained of herein were done by and for the benefit of MSN.

545. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XVI
INFRINGEMENT OF THE '572 PATENT BY MSN

546. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

547. On information and belief, MSN filed MSN's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '572 patent.

548. On information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

549. On information and belief, in MSN's ANDA, MSN has represented to the FDA that MSN's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

550. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's Generic Product before

the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

551. After FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing MSN's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of MSN's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

552. On information and belief, MSN knows, or should know, and intends that healthcare providers will prescribe and patients will take MSN's Generic Product for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '572 patent.

553. On information and belief, MSN had knowledge of the '572 patent and, by its promotional activities and proposed package insert for MSN's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

554. On information and belief, MSN is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use MSN's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

555. The offering to sell, sale, making, and/or importation of MSN's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally

or under the doctrine of equivalents. MSN has knowledge and is aware of the '572 patent, as evidenced by MSN's September 27, 2022 Notice Letter.

556. On information and belief, if MSN's ANDA is approved, MSN intends to and will offer to sell, sell, and/or import in the United States MSN's Generic Product.

557. On information and belief, MSN's actions relating to MSN's ANDA complained of herein were done by and for the benefit of MSN.

558. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XVII
INFRINGEMENT OF THE '351 PATENT BY MSN

559. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

560. On information and belief, MSN filed MSN's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '351 patent.

561. On information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

562. On information and belief, in MSN's ANDA, MSN has represented to the FDA that MSN's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

563. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

564. After FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing MSN's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of MSN's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

565. On information and belief, MSN knows, or should know, and intends that healthcare providers will prescribe and patients will take MSN's Generic Product for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '351 patent.

566. On information and belief, MSN had knowledge of the '351 patent and, by its promotional activities and proposed package insert for MSN's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

567. On information and belief, MSN is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use MSN's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

568. The offering to sell, sale, making, and/or importation of MSN's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. MSN has knowledge and is aware of the '351 patent, as evidenced by MSN's September 27, 2022 Notice Letter.

569. On information and belief, if MSN's ANDA is approved, MSN intends to and will offer to sell, sell, and/or import in the United States MSN's Generic Product.

570. On information and belief, MSN's actions relating to MSN's ANDA complained of herein were done by and for the benefit of MSN.

571. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XVIII
INFRINGEMENT OF THE '551 PATENT BY MSN

572. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

573. On information and belief, MSN filed MSN's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '551 patent.

574. On information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

575. On information and belief, in MSN's ANDA, MSN has represented to the FDA that MSN's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

576. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

577. After FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing MSN's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of MSN's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

578. On information and belief, MSN knows, or should know, and intends that healthcare providers will prescribe and patients will take MSN's Generic Product for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '551 patent.

579. On information and belief, MSN had knowledge of the '551 patent and, by its promotional activities and proposed package insert for MSN's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

580. On information and belief, MSN is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use MSN's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

581. The offering to sell, sale, making, and/or importation of MSN's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. MSN has knowledge and is aware of the '551 patent, as evidenced by MSN's September 27, 2022 Notice Letter.

582. On information and belief, if MSN's ANDA is approved, MSN intends to and will offer to sell, sell, and/or import in the United States MSN's Generic Product.

583. MSN has had and continues to have knowledge that MSN's Generic Product is especially adapted for a use that infringes the '551 patent.

584. On information and belief, MSN has had and continues to have knowledge that there is no substantial non-infringing use for MSN's Generic Product.

585. On information and belief, MSN's actions relating to MSN's ANDA complained of herein were done by and for the benefit of MSN.

586. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XIX
INFRINGEMENT OF THE '927 PATENT BY PRINSTON

587. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

588. On information and belief, Prinston filed Prinston's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '927 patent.

589. On information and belief, Prinston filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

590. On information and belief, in Prinston's ANDA, Prinston has represented to the FDA that Prinston's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

591. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Prinston's ANDA seeking approval for the commercial manufacture, use, or sale of Prinston's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

592. After FDA approval of Prinston's ANDA, Prinston will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Prinston's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Prinston's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

593. On information and belief, Prinston knows, or should know, and intends that healthcare providers will prescribe and patients will take Prinston's Generic Product for which approval is sought in Prinston's ANDA, and therefore will infringe at least one claim in the '927 patent.

594. On information and belief, Prinston had knowledge of the '927 patent and, by its promotional activities and proposed package insert for Prinston's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

595. On information and belief, Prinston is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Prinston's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

596. The offering to sell, sale, making, and/or importation of Prinston's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. Prinston has knowledge and is aware of the '927 patent, as evidenced by Prinston's September 13, 2022 Notice Letter.

597. On information and belief, if Prinston's ANDA is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

598. Prinston has had and continues to have knowledge that Prinston's Generic Product is especially adapted for a use that infringes the '927 patent.

599. On information and belief, Prinston has had and continues to have knowledge that there is no substantial non-infringing use for Prinston's Generic Product.

600. On information and belief, Prinston's actions relating to Prinston's ANDA complained of herein were done by and for the benefit of Prinston.

601. Plaintiffs will be irreparably harmed if Prinston is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XX
INFRINGEMENT OF THE '983 PATENT BY PRINSTON

602. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

603. On information and belief, Prinston filed Prinston's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '983 patent.

604. On information and belief, Prinston filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

605. On information and belief, in Prinston's ANDA, Prinston has represented to the FDA that Prinston's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

606. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Prinston's ANDA seeking approval for the commercial manufacture, use, or sale of Prinston's Generic Product before the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

607. After FDA approval of Prinston's ANDA, Prinston will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Prinston's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under

§ 271(c), unless this Court orders that the effective date of any FDA approval of Prinston's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

608. On information and belief, Prinston knows, or should know, and intends that healthcare providers will prescribe and patients will take Prinston's Generic Product for which approval is sought in Prinston's ANDA, and therefore will infringe at least one claim in the '983 patent.

609. On information and belief, Prinston had knowledge of the '983 patent and, by its promotional activities and proposed package insert for Prinston's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

610. On information and belief, Prinston is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Prinston's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

611. The offering to sell, sale, making, and/or importation of Prinston's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents. Prinston has knowledge and is aware of the '983 patent, as evidenced by Prinston's September 13, 2022 Notice Letter.

612. On information and belief, if Prinston's ANDA is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

613. Prinston has had and continues to have knowledge that Prinston's Generic Product is especially adapted for a use that infringes the '983 patent.

614. On information and belief, Prinston has had and continues to have knowledge that there is no substantial non-infringing use for Prinston's Generic Product.

615. On information and belief, Prinston's actions relating to Prinston's ANDA complained of herein were done by and for the benefit of Prinston.

616. Plaintiffs will be irreparably harmed if Prinston is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXI
INFRINGEMENT OF THE '551 PATENT BY PRINSTON

617. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

618. On information and belief, Prinston filed Prinston's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '551 patent.

619. On information and belief, Prinston filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

620. On information and belief, in Prinston's ANDA, Prinston has represented to the FDA that Prinston's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

621. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Prinston's ANDA seeking approval for the commercial manufacture, use, or sale of Prinston's Generic Product

before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

622. After FDA approval of Prinston's ANDA, Prinston will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Prinston's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Prinston's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

623. On information and belief, Prinston knows, or should know, and intends that healthcare providers will prescribe and patients will take Prinston's Generic Product for which approval is sought in Prinston's ANDA, and therefore will infringe at least one claim in the '551 patent.

624. On information and belief, Prinston had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Prinston's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

625. On information and belief, Prinston is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Prinston's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

626. The offering to sell, sale, making, and/or importation of Prinston's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally

or under the doctrine of equivalents. Prinston has knowledge and is aware of the '551 patent, as evidenced by Prinston's September 13, 2022 Notice Letter.

627. On information and belief, if Prinston's ANDA is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

628. Prinston has had and continues to have knowledge that Prinston's Generic Product is especially adapted for a use that infringes the '551 patent.

629. On information and belief, Prinston has had and continues to have knowledge that there is no substantial non-infringing use for Prinston's Generic Product.

630. On information and belief, Prinston's actions relating to Prinston's ANDA complained of herein were done by and for the benefit of Prinston.

631. Plaintiffs will be irreparably harmed if Prinston is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXII
INFRINGEMENT OF THE '927 PATENT BY SANDOZ

632. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

633. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '927 patent.

634. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

635. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

636. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

637. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

638. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '927 patent.

639. On information and belief, Sandoz had knowledge of the '927 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

640. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

641. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '927 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

642. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

643. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '927 patent.

644. On information and belief, Sandoz has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

645. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

646. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXIII
INFRINGEMENT OF THE '211 PATENT BY SANDOZ

647. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

648. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '211 patent.

649. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '211 patent are purportedly invalid, unenforceable, and/or not infringed.

650. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

651. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration date of the '211 patent, constitutes infringement, either literally or under the doctrine of equivalents.

652. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '211 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '211 patent and any additional periods of exclusivity.

653. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '211 patent.

654. On information and belief, Sandoz had knowledge of the '211 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '211 patent, either literally or under the doctrine of equivalents.

655. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '211 patent.

656. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '211 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '211 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

657. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

658. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '211 patent.

659. On information and belief, Sandoz has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

660. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

661. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '211 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXIV
INFRINGEMENT OF THE '983 PATENT BY SANDOZ

662. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

663. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '983 patent.

664. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

665. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

666. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

667. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under

§ 271(c), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

668. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '983 patent.

669. On information and belief, Sandoz had knowledge of the '983 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

670. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

671. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '983 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

672. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

673. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '983 patent.

674. On information and belief, Sandoz has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

675. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

676. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXV
INFRINGEMENT OF THE '572 PATENT BY SANDOZ

677. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

678. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '572 patent.

679. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

680. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

681. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before

the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

682. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

683. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '572 patent.

684. On information and belief, Sandoz had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

685. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

686. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally

or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '572 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

687. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

688. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

689. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXVI
INFRINGEMENT OF THE '351 PATENT BY SANDOZ

690. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

691. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '351 patent.

692. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

693. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

694. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

695. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

696. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '351 patent.

697. On information and belief, Sandoz had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

698. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

699. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '351 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

700. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

701. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

702. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXVII
INFRINGEMENT OF THE '551 PATENT BY SANDOZ

703. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

704. On information and belief, Sandoz filed Sandoz's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '551 patent.

705. On information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

706. On information and belief, in Sandoz's ANDA, Sandoz has represented to the FDA that Sandoz's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

707. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sandoz's ANDA seeking approval for the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

708. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sandoz's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

709. On information and belief, Sandoz knows, or should know, and intends that healthcare providers will prescribe and patients will take Sandoz's Generic Product for which approval is sought in Sandoz's ANDA, and therefore will infringe at least one claim in the '551 patent.

710. On information and belief, Sandoz had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Sandoz's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

711. On information and belief, Sandoz is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Sandoz's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

712. The offering to sell, sale, making, and/or importation of Sandoz's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '551 patent, as evidenced by Sandoz's September 29, 2022 Notice Letter.

713. On information and belief, if Sandoz's ANDA is approved, Sandoz intends to and will offer to sell, sell, and/or import in the United States Sandoz's Generic Product.

714. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '551 patent.

715. On information and belief, Sandoz has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

716. On information and belief, Sandoz's actions relating to Sandoz's ANDA complained of herein were done by and for the benefit of Sandoz.

717. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXVIII
INFRINGEMENT OF THE '927 PATENT BY SUN

718. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

719. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '927 patent.

720. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '927 patent are purportedly invalid, unenforceable, and/or not infringed.

721. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

722. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before the expiration date of the '927 patent, constitutes infringement, either literally or under the doctrine of equivalents.

723. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '927 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '927 patent and any additional periods of exclusivity.

724. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '927 patent.

725. On information and belief, Sun had knowledge of the '927 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

726. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '927 patent.

727. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '927 patent, as evidenced by Sun's September 16, 2022 Notice Letter.

728. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

729. Sun has had and continues to have knowledge that Sun's Generic Product is especially adapted for a use that infringes the '927 patent.

730. On information and belief, Sun has had and continues to have knowledge that there is no substantial non-infringing use for Sun's Generic Product.

731. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

732. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '927 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXIX
INFRINGEMENT OF THE '983 PATENT BY SUN

733. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

734. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '983 patent.

735. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '983 patent are purportedly invalid, unenforceable, and/or not infringed.

736. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

737. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before the expiration date of the '983 patent, constitutes infringement, either literally or under the doctrine of equivalents.

738. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '983 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '983 patent and any additional periods of exclusivity.

739. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '983 patent.

740. On information and belief, Sun had knowledge of the '983 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents.

741. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '983 patent.

742. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '983 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '983 patent, as evidenced by Sun's September 16, 2022 Notice Letter.

743. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

744. Sun has had and continues to have knowledge that Sun's Generic Product is especially adapted for a use that infringes the '983 patent.

745. On information and belief, Sun has had and continues to have knowledge that there is no substantial non-infringing use for Sun's Generic Product.

746. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

747. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '983 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXX
INFRINGEMENT OF THE '572 PATENT BY SUN

748. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

749. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '572 patent.

750. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

751. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

752. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

753. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

754. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '572 patent.

755. On information and belief, Sun had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

756. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

757. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '572 patent, as evidenced by Sun's September 16, 2022 Notice Letter.

758. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

759. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

760. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXI
INFRINGEMENT OF THE '351 PATENT BY SUN

761. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

762. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '351 patent.

763. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

764. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

765. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

766. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

767. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '351 patent.

768. On information and belief, Sun had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

769. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

770. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '351 patent, as evidenced by Sun's September 16, 2022 Notice Letter.

771. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

772. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

773. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXII
INFRINGEMENT OF THE '551 PATENT BY SUN

774. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

775. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '551 patent.

776. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

777. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

778. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

779. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

780. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '551 patent.

781. On information and belief, Sun had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

782. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

783. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '551 patent, as evidenced by Sun's September 16, 2022 Notice Letter.

784. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

785. Sun has had and continues to have knowledge that Sun's Generic Product is especially adapted for a use that infringes the '551 patent.

786. On information and belief, Sun has had and continues to have knowledge that there is no substantial non-infringing use for Sun's Generic Product.

787. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

788. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXIII
INFRINGEMENT OF THE '572 PATENT BY TEVA

789. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

790. On information and belief, Teva filed Teva's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Teva's Generic Product in the United States before the expiration of the '572 patent.

791. On information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

792. On information and belief, in Teva's ANDA, Teva has represented to the FDA that Teva's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

793. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Teva's ANDA seeking approval for the commercial manufacture, use, or sale of Teva's Generic Product before the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

794. After FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Teva's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

795. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Generic Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '572 patent.

796. On information and belief, Teva had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Teva's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

797. On information and belief, Teva is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Teva's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

798. The offering to sell, sale, making, and/or importation of Teva's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally

or under the doctrine of equivalents. Teva has knowledge and is aware of the '572 patent, as evidenced by Teva's September 12, 2022 Notice Letter.

799. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Generic Product.

800. On information and belief, Teva's actions relating to Teva's ANDA complained of herein were done by and for the benefit of Teva.

801. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXIV
INFRINGEMENT OF THE '351 PATENT BY TEVA

802. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

803. On information and belief, Teva filed Teva's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Teva's Generic Product in the United States before the expiration of the '351 patent.

804. On information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

805. On information and belief, in Teva's ANDA, Teva has represented to the FDA that Teva's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

806. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Teva's ANDA seeking approval for the commercial manufacture, use, or sale of Teva's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

807. After FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Teva's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

808. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Generic Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '351 patent.

809. On information and belief, Teva had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Teva's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

810. On information and belief, Teva is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Teva's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

811. The offering to sell, sale, making, and/or importation of Teva's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally

or under the doctrine of equivalents. Teva has knowledge and is aware of the '351 patent, as evidenced by Teva's September 12, 2022 Notice Letter.

812. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Generic Product.

813. On information and belief, Teva's actions relating to Teva's ANDA complained of herein were done by and for the benefit of Teva.

814. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXV
INFRINGEMENT OF THE '551 PATENT BY TEVA

815. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

816. On information and belief, Teva filed Teva's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Teva's Generic Product in the United States before the expiration of the '551 patent.

817. On information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

818. On information and belief, in Teva's ANDA, Teva has represented to the FDA that Teva's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

819. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Teva's ANDA seeking approval for the commercial manufacture, use, or sale of Teva's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

820. After FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Teva's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

821. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Generic Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '551 patent.

822. On information and belief, Teva had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Teva's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

823. On information and belief, Teva is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Teva's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

824. The offering to sell, sale, making, and/or importation of Teva's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally

or under the doctrine of equivalents. Teva has knowledge and is aware of the '551 patent, as evidenced by Teva's September 12, 2022 Notice Letter.

825. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Generic Product.

826. Teva has had and continues to have knowledge that Teva's Generic Product is especially adapted for a use that infringes the '551 patent.

827. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva's Generic Product.

828. On information and belief, Teva's actions relating to Teva's ANDA complained of herein were done by and for the benefit of Teva.

829. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXVI
INFRINGEMENT OF THE '572 PATENT BY ZENARA

830. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

831. On information and belief, Zenara filed Zenara's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zenara's Generic Product in the United States before the expiration of the '572 patent.

832. On information and belief, Zenara filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '572 patent are purportedly invalid, unenforceable, and/or not infringed.

833. On information and belief, in Zenara's ANDA, Zenara has represented to the FDA that Zenara's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

834. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zenara's ANDA seeking approval for the commercial manufacture, use, or sale of Zenara's Generic Product before the expiration date of the '572 patent, constitutes infringement, either literally or under the doctrine of equivalents.

835. After FDA approval of Zenara's ANDA, Zenara will infringe one or more claims of the '572 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zenara's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Zenara's ANDA shall be no earlier than the expiration of the '572 patent and any additional periods of exclusivity.

836. On information and belief, Zenara knows, or should know, and intends that healthcare providers will prescribe and patients will take Zenara's Generic Product for which approval is sought in Zenara's ANDA, and therefore will infringe at least one claim in the '572 patent.

837. On information and belief, Zenara had knowledge of the '572 patent and, by its promotional activities and proposed package insert for Zenara's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents.

838. On information and belief, Zenara is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Zenara's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '572 patent.

839. The offering to sell, sale, making, and/or importation of Zenara's Generic Product would actively induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents. Zenara has knowledge and is aware of the '572 patent, as evidenced by Zenara's September 28, 2022 Notice Letter.

840. On information and belief, if Zenara's ANDA is approved, Zenara intends to and will offer to sell, sell, and/or import in the United States Zenara's Generic Product.

841. On information and belief, Zenara's actions relating to Zenara's ANDA complained of herein were done by and for the benefit of Zenara.

842. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing or actively inducing infringement of at least one claim of the '572 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXVII
INFRINGEMENT OF THE '351 PATENT BY ZENARA

843. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

844. On information and belief, Zenara filed Zenara's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zenara's Generic Product in the United States before the expiration of the '351 patent.

845. On information and belief, Zenara filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '351 patent are purportedly invalid, unenforceable, and/or not infringed.

846. On information and belief, in Zenara's ANDA, Zenara has represented to the FDA that Zenara's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

847. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zenara's ANDA seeking approval for the commercial manufacture, use, or sale of Zenara's Generic Product before the expiration date of the '351 patent, constitutes infringement, either literally or under the doctrine of equivalents.

848. After FDA approval of Zenara's ANDA, Zenara will infringe one or more claims of the '351 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zenara's Generic Product, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Zenara's ANDA shall be no earlier than the expiration of the '351 patent and any additional periods of exclusivity.

849. On information and belief, Zenara knows, or should know, and intends that healthcare providers will prescribe and patients will take Zenara's Generic Product for which approval is sought in Zenara's ANDA, and therefore will infringe at least one claim in the '351 patent.

850. On information and belief, Zenara had knowledge of the '351 patent and, by its promotional activities and proposed package insert for Zenara's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents.

851. On information and belief, Zenara is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Zenara's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '351 patent.

852. The offering to sell, sale, making, and/or importation of Zenara's Generic Product would actively induce infringement of at least one of the claims of the '351 patent, either literally or under the doctrine of equivalents. Zenara has knowledge and is aware of the '351 patent, as evidenced by Zenara's September 28, 2022 Notice Letter.

853. On information and belief, if Zenara's ANDA is approved, Zenara intends to and will offer to sell, sell, and/or import in the United States Zenara's Generic Product.

854. On information and belief, Zenara's actions relating to Zenara's ANDA complained of herein were done by and for the benefit of Zenara.

855. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing or actively inducing infringement of at least one claim of the '351 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT XXXVIII
INFRINGEMENT OF THE '551 PATENT BY ZENARA

856. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

857. On information and belief, Zenara filed Zenara's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zenara's Generic Product in the United States before the expiration of the '551 patent.

858. On information and belief, Zenara filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '551 patent are purportedly invalid, unenforceable, and/or not infringed.

859. On information and belief, in Zenara's ANDA, Zenara has represented to the FDA that Zenara's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' ORILISSA® Tablets.

860. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zenara's ANDA seeking approval for the commercial manufacture, use, or sale of Zenara's Generic Product before the expiration date of the '551 patent, constitutes infringement, either literally or under the doctrine of equivalents.

861. After FDA approval of Zenara's ANDA, Zenara will infringe one or more claims of the '551 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zenara's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zenara's ANDA shall be no earlier than the expiration of the '551 patent and any additional periods of exclusivity.

862. On information and belief, Zenara knows, or should know, and intends that healthcare providers will prescribe and patients will take Zenara's Generic Product for which approval is sought in Zenara's ANDA, and therefore will infringe at least one claim in the '551 patent.

863. On information and belief, Zenara had knowledge of the '551 patent and, by its promotional activities and proposed package insert for Zenara's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents.

864. On information and belief, Zenara is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because

healthcare professionals and/or patients will use Zenara's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '551 patent.

865. The offering to sell, sale, making, and/or importation of Zenara's Generic Product would actively induce infringement of at least one of the claims of the '551 patent, either literally or under the doctrine of equivalents. Zenara has knowledge and is aware of the '551 patent, as evidenced by Zenara's September 28, 2022 Notice Letter.

866. On information and belief, if Zenara's ANDA is approved, Zenara intends to and will offer to sell, sell, and/or import in the United States Zenara's Generic Product.

867. Zenara has had and continues to have knowledge that Zenara's Generic Product is especially adapted for a use that infringes the '551 patent.

868. On information and belief, Zenara has had and continues to have knowledge that there is no substantial non-infringing use for Zenara's Generic Product.

869. On information and belief, Zenara's actions relating to Zenara's ANDA complained of herein were done by and for the benefit of Zenara.

870. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing or actively inducing infringement of at least one claim of the '551 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

Alkem

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Alkem has infringed at least one claim of the '572, '351, and '551 patents through Alkem's submission of ANDA

No. 217668 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem's Generic Product in the United States before the expiration of the '572, '351, and '551 patents;

B. The entry of judgment that Alkem's making, using, offering to sell, selling, or importing Alkem's Generic Product prior to the expiration of the '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

C. A declaration under 28 U.S.C. § 2201 that if Alkem, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Alkem's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. The issuance of an order that the effective date of any FDA approval of Alkem's Generic Product shall be no earlier than the expiration date of the '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a permanent injunction, enjoining Alkem and all persons acting in concert with Alkem from commercially manufacturing, using, offering for sale, or selling Alkem's Generic Product within the United States, or importing Alkem's Generic Product into the United States, until the expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a permanent injunction, enjoining Alkem and all persons acting in concert with Alkem from seeking, obtaining, or maintaining approval of the ANDA until the

expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

H. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Hetero

J. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of the '927, '983, '572, '351, and '551 patents through Hetero's submission of ANDA No. 217690 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '927, '983, '572, '351, and '551 patents;

K. The entry of judgment that Hetero's making, using, offering to sell, selling, or importing Hetero's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

L. A declaration under 28 U.S.C. § 2201 that if Hetero, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Hetero's

Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

M. The issuance of an order that the effective date of any FDA approval of Hetero's Generic Product shall be no earlier than the expiration date of the '927, '983, '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

N. The entry of a permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, or selling Hetero's Generic Product within the United States, or importing Hetero's Generic Product into the United States, until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

Q. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

R. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Lupin

S. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '927, '983, '572, '351, and '551 patents through Lupin's submission of ANDA No. 217712 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Lupin's Generic Product in the United States before the expiration of the '927, '983, '572, '351, and '551 patents;

T. The entry of judgment that Lupin's making, using, offering to sell, selling, or importing Lupin's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

U. A declaration under 28 U.S.C. § 2201 that if Lupin, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Lupin's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

V. The issuance of an order that the effective date of any FDA approval of Lupin's Generic Product shall be no earlier than the expiration date of the '927, '983, '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

W. The entry of a permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from commercially manufacturing, using, offering for sale, or selling Lupin's Generic Product within the United States, or importing Lupin's Generic Product into the United States, until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

X. The entry of a permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Y. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

Z. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

AA. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

MSN

BB. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that MSN has infringed at least one claim of the '927, '983, '572, '351, and '551 patents through MSN's submission of ANDA No. 217716 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's Generic Product in the United States before the expiration of the '927, '983, '572, '351, and '551 patents;

CC. The entry of judgment that MSN's making, using, offering to sell, selling, or importing MSN's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

DD. A declaration under 28 U.S.C. § 2201 that if MSN, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its

behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of MSN's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

EE. The issuance of an order that the effective date of any FDA approval of MSN's Generic Product shall be no earlier than the expiration date of the '927, '983, '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

FF. The entry of a permanent injunction, enjoining MSN and all persons acting in concert with MSN from commercially manufacturing, using, offering for sale, or selling MSN's Generic Product within the United States, or importing MSN's Generic Product into the United States, until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

GG. The entry of a permanent injunction, enjoining MSN and all persons acting in concert with MSN from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

HH. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

II. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

JJ. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Prinston

KK. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Prinston has infringed at least one claim of the '927, '983, '551 patents through Prinston's submission of ANDA No. 217296 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '927, '983, and '551 patents;

LL. The entry of judgment that Prinston's making, using, offering to sell, selling, or importing Prinston's Generic Product prior to the expiration of the '927, '983, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '983, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

MM. A declaration under 28 U.S.C. § 2201 that if Prinston, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Prinston's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

NN. The issuance of an order that the effective date of any FDA approval of Prinston's Generic Product shall be no earlier than the expiration date of the '927, '983, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

OO. The entry of a permanent injunction, enjoining Prinston and all persons acting in concert with Prinston from commercially manufacturing, using, offering for sale, or selling Prinston's Generic Product within the United States, or importing Prinston's Generic Product into the United States, until the expiration of the '927, '983, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

PP. The entry of a permanent injunction, enjoining Prinston and all persons acting in concert with Prinston from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '983, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

QQ. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

RR. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

SS. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Sandoz

TT. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Sandoz has infringed at least one claim of the '927, '211, '983, '572, '351, and '551 patents through Sandoz's submission of ANDA No. 217551 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Sandoz's Generic Product in the United States before the expiration of the '927, '211, '983, '572, '351, and '551 patents;

UU. The entry of judgment that Sandoz's making, using, offering to sell, selling, or importing Sandoz's Generic Product prior to the expiration of the '927, '211, '983, '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '211, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

VV. A declaration under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with

it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Sandoz's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

WW. The issuance of an order that the effective date of any FDA approval of Sandoz's Generic Product shall be no earlier than the expiration date of the '927, '211, '983, '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

XX. The entry of a permanent injunction, enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, or selling Sandoz's Generic Product within the United States, or importing Sandoz's Generic Product into the United States, until the expiration of the '927, '211, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

YY. The entry of a permanent injunction, enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '211, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

ZZ. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

AAA. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

BBB. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Sun

CCC. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Sun has infringed at least one claim of the '927, '983, '572, '351, and '551 patents through Sun's submission of ANDA No. 215804 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '927, '983, '572, '351, and '551 patents;

DDD. The entry of judgment that Sun's making, using, offering to sell, selling, or importing Sun's Generic Product prior to the expiration of the '927, '983, '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '927, '983, '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

EEE. A declaration under 28 U.S.C. § 2201 that if Sun, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Sun's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

FFF. The issuance of an order that the effective date of any FDA approval of Sun's Generic Product shall be no earlier than the expiration date of the '927, '983, '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

GGG. The entry of a permanent injunction, enjoining Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, or selling Sun's Generic Product within the United States, or importing Sun's Generic Product into the United States, until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

HHH. The entry of a permanent injunction, enjoining Sun and all persons acting in concert with Sun from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '927, '983, '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

III. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

JJJ. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

KKK. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Teva

LLL. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '572, '351, and '551 patents through Teva's submission of ANDA No. 217642 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Teva's Generic Product in the United States before the expiration of the '572, '351, and '551 patents;

MMM. The entry of judgment that Teva's making, using, offering to sell, selling, or importing Teva's Generic Product prior to the expiration of the '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

NNN. A declaration under 28 U.S.C. § 2201 that if Teva, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its

behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Teva's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

OOO. The issuance of an order that the effective date of any FDA approval of Teva's Generic Product shall be no earlier than the expiration date of the '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

PPP. The entry of a permanent injunction, enjoining Teva and all persons acting in concert with Teva from commercially manufacturing, using, offering for sale, or selling Teva's Generic Product within the United States, or importing Teva's Generic Product into the United States, until the expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

QQQ. The entry of a permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

RRR. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

SSS. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

TTT. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Zenara

UUU. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Zenara has infringed at least one claim of the '572, '351, and '551 patents through Zenara's submission of ANDA No. 217760 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Zenara's Generic Product in the United States before the expiration of the '572, '351, and '551 patents;

VVV. The entry of judgment that Zenara's making, using, offering to sell, selling, or importing Zenara's Generic Product prior to the expiration of the '572, '351, and '551 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '572, '351, and '551 patents under 35 U.S.C. § 271(a), (b), and/or (c);

WWW. A declaration under 28 U.S.C. § 2201 that if Zenara, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Zenara's Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

XXX. The issuance of an order that the effective date of any FDA approval of Zenara's Generic Product shall be no earlier than the expiration date of the '572, '351, and '551 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

YYY. The entry of a permanent injunction, enjoining Zenara and all persons acting in concert with Zenara from commercially manufacturing, using, offering for sale, or selling Zenara's Generic Product within the United States, or importing Zenara's Generic Product into the United States, until the expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

ZZZ. The entry of a permanent injunction, enjoining Zenara and all persons acting in concert with Zenara from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '572, '351, and '551 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

AAAA. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

BBBB. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

CCCC. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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