

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., )  
                        )  
Plaintiff,         )  
                        )  
v.                   ) C.A. No. \_\_\_\_\_  
                        )  
SANDOZ INC.,      )  
                        )  
Defendant.         )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff AbbVie Inc. (“AbbVie” or “Plaintiff”), by its attorneys, brings this action against Defendant Sandoz Inc. (“Sandoz”), and alleges as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement of U.S. Patent Nos. 11,542,239 (“the ’239 patent”), 11,690,845 (“the ’845 patent”), 11,690,854 (“the ’854 patent”), and 11,707,464 (“the ’464 patent”) 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 Sandoz’s recent submission to the United States Food and Drug Administration (“FDA”) of an Abbreviated New Drug Application (“ANDA”) seeking approval to market generic versions of Plaintiff’s 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®. 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 ’239, ’845, ’854, and ’464 patents.

2. Sandoz has infringed one or more claims of the '239, '845, '854, and '464 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 '239, '845, '854, and '464 patents, or any extensions thereof. Sandoz will infringe one or more claims of the '239, '845, '854, and '464 patents under 35 U.S.C. § 271(a), (b), and/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 '239, '845, '854, and '464 patents, or any extensions thereof.

3. Plaintiff AbbVie Inc., along with AbbVie Ltd and Neurocrine Biosciences, Inc., previously filed a separate action in this Court against Sandoz Inc. for patent infringement relating to ANDA No. 217551, which included counts for 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"). *AbbVie Inc., et al. v. Alkem Laboratories Limited, et al.*, C.A. No. 22-1423-RGA-JLH (consolidated) (the "First Suit") was filed on October 27, 2022. The First Suit was filed in response to a letter from Sandoz dated September 29, 2022 ("Sandoz's First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217551 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '927 patent, the '211 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent. The First Suit included counts for infringement of the '927 patent, the '211 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent.

4. Based on information and belief, Sandoz is maintaining its certification as to the '927 patent, the '211 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent

set out in Sandoz's First Notice Letter. Thus, Plaintiffs AbbVie Inc., AbbVie Ltd, and Neurocrine Biosciences, Inc. will continue to prosecute all infringement counts presented in the First Suit.

**ORILISSA®**

5. 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®.

6. 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.

7. 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.

8. ORILISSA® was approved by the FDA on July 23, 2018, 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).

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

10. The '239, '845, '854, and '464 patents are listed in the Orange Book for ORILISSA®.

## **THE PARTIES**

11. Plaintiff AbbVie 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 is the assignee and owner of the '239, '845, '854, and '464 patents. AbbVie holds NDA No. 210450 for ORILISSA®. AbbVie 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 women's health.

12. AbbVie markets, distributes, and sells therapeutic drug products, including ORILISSA®, in this judicial district and throughout the United States.

13. 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.

14. On information and belief, Sandoz 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.

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

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

**JURISDICTION AND VENUE**

17. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

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

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

20. 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.

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

22. On information and belief, Sandoz 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.

23. 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.

24. 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. 25, 2023). 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.

25. 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").

26. 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 Plaintiff in this District.

27. On information and belief, Sandoz 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.

28. 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 '239, '845, '854, and '464 patents.

29. On information and belief and as indicated by a letter dated October 13, 2023, sent by Sandoz to Plaintiff 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.

30. 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.

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

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

33. 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., AbbVie Inc., et al. v. Alkem Laboratories Limited, et al.*, No. 22-1423-RGA-JLH; *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.

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

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

### **FACTUAL BACKGROUND**

#### **The NDA**

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

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

38. 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**

39. The '239 patent, titled “Elagolix Sodium Compositions and Processes” was duly and legally issued by the United States Patent and Trademark Office on January 3, 2023. A true and correct copy of the '239 patent is attached as Exhibit A.

40. AbbVie owns the rights to the '239 patent. The '239 patent will expire on July 23, 2039.

41. The '239 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.

42. The '845 patent, titled “Methods of Administering Elagolix” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the '845 patent is attached as Exhibit B.

43. AbbVie owns the rights to the '845 patent. The '845 patent will expire on August 27, 2040.

44. The '845 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.

45. The '854 patent, titled “Methods of Treating Heavy Menstrual Bleeding” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the '854 patent is attached as Exhibit C.

46. AbbVie owns the rights to the '854 patent. The '854 patent will expire on April 19, 2038.

47. The '854 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.

48. The '464 patent, titled "Methods of Treating Heavy Menstrual Bleeding" was duly and legally issued by the United States Patent and Trademark Office on July 25, 2023. A true and correct copy of the '464 patent is attached as Exhibit D.

49. AbbVie owns the rights to the '464 patent. The '464 patent will expire on March 14, 2034.

50. The '464 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.

#### **Sandoz's ANDA No. 217551**

51. 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 Plaintiff's ORILISSA® (elagolix sodium) Tablets.

52. ANDA No. 217551 contains Paragraph IV certifications, alleging that the claims of the '239, '845, '854, and '464 patents are invalid, unenforceable, and/or would not be infringed by Sandoz's Generic Product.

53. AbbVie received a letter sent by Sandoz, dated October 13, 2023, purporting to be an "Updated Notice of Paragraph IV Certification" for ANDA No. 217551 ("Sandoz's Second 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 Second Notice Letter notified AbbVie that Sandoz had filed ANDA No. 217551, seeking approval to market Sandoz's Generic Product prior to the expiration of the '239, '845, '854, and '464 patents.

54. Plaintiff commenced this action within 45 days of receiving Sandoz's October 13, 2023 Notice Letter.

55. 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 '239, '845, '854, and '464 patents expire.

**COUNT I**  
**INFRINGEMENT OF THE '239 PATENT BY SANDOZ**

56. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

57. 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 '239 patent.

58. 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 '239 patent are purportedly invalid, unenforceable, and/or not infringed.

59. 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 Plaintiff's ORILISSA®.

60. 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 '239 patent, constitutes infringement, either literally or under the doctrine of equivalents.

61. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '239 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 '239 patent and any additional periods of exclusivity.

62. 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 '239 patent.

63. On information and belief, Sandoz had knowledge of the '239 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 '239 patent, either literally or under the doctrine of equivalents.

64. 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 '239 patent.

65. 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 '239 patent, either literally

or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '239 patent, as evidenced by Sandoz's October 13, 2023 Notice Letter.

66. 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.

67. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '239 patent.

68. 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.

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

70. Plaintiff will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '239 patent. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

**COUNT II**  
**INFRINGEMENT OF THE '845 PATENT BY SANDOZ**

71. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

72. 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 '845 patent.

73. 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 '845 patent are purportedly invalid, unenforceable, and/or not infringed.

74. 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 Plaintiff's ORILISSA®.

75. 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 '845 patent, constitutes infringement, either literally or under the doctrine of equivalents.

76. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '845 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 '845 patent and any additional periods of exclusivity.

77. 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 '845 patent.

78. On information and belief, Sandoz had knowledge of the '845 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 '845 patent, either literally or under the doctrine of equivalents.

79. 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 '845 patent.

80. 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 '845 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '845 patent, as evidenced by Sandoz's October 13, 2023 Notice Letter.

81. 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.

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

83. Plaintiff will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '845 patent. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

**COUNT III**  
**INFRINGEMENT OF THE '854 PATENT BY SANDOZ**

84. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

85. 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 '854 patent.

86. 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 '854 patent are purportedly invalid, unenforceable, and/or not infringed.

87. 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 Plaintiff's ORILISSA®.

88. 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 '854 patent, constitutes infringement, either literally or under the doctrine of equivalents.

89. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '854 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 '854 patent and any additional periods of exclusivity.

90. 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 '854 patent.

91. On information and belief, Sandoz had knowledge of the '854 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 '854 patent, either literally or under the doctrine of equivalents.

92. 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 '854 patent.

93. 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 '854 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '854 patent, as evidenced by Sandoz's October 13, 2023 Notice Letter.

94. 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.

95. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '854 patent.

96. 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.

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

98. Plaintiff will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '854 patent. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

**COUNT IV**  
**INFRINGEMENT OF THE '464 PATENT BY SANDOZ**

99. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

100. 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 '464 patent.

101. 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 '464 patent are purportedly invalid, unenforceable, and/or not infringed.

102. 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 Plaintiff's ORILISSA®.

103. 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 '464 patent, constitutes infringement, either literally or under the doctrine of equivalents.

104. After FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '464 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 '464 patent and any additional periods of exclusivity.

105. 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 '464 patent.

106. On information and belief, Sandoz had knowledge of the '464 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 '464 patent, either literally or under the doctrine of equivalents.

107. 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 '464 patent.

108. 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 '464 patent, either literally or under the doctrine of equivalents. Sandoz has knowledge and is aware of the '464 patent, as evidenced by Sandoz's October 13, 2023 Notice Letter.

109. 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.

110. Sandoz has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '464 patent.

111. 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.

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

113. Plaintiff will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing infringement of at least one claim of the '464 patent. Pursuant to 35 U.S.C. § 283,

Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

**REQUEST FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Sandoz has infringed at least one claim of the '239, '845, '854, and '464 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 '239, '845, '854, and '464 patents;

B. 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 '239, '845, '854, and '464 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '239, '845, '854, and '464 patents under 35 U.S.C. § 271(a), (b), and/or (c);

C. 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);

D. 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 '239, '845, '854, and '464 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 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 '239, '845, '854, and '464 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. 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 '239, '845, '854, and '464 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 Plaintiff of its 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 Plaintiff of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiff of any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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