IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ZENARA PHARMA PRIVATE LIMITED and BIOPHORE INDIA PHARMACEUTICALS PRIVATE LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AbbVie Inc. ("AbbVie" or "Plaintiff"), by its attorneys, brings this action against Defendants Zenara Pharma Private Limited ("Zenara Pharma") and Biophore India Pharmaceuticals Private Ltd. ("Biophore") (collectively, "Zenara"), and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 11,542,239 ("the '239 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 Zenara'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®. 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 '239 patent.

2. Zenara has infringed one or more claims of the '239 patent 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 '239 patent, or any extensions thereof. Zenara will infringe one or more claims of the '239 patent 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 '239 patent, 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 Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Ltd. for patent infringement relating to ANDA No. 217760, which included counts for infringement of U.S. Patent Nos. 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 (the "First Suit") was filed on October 27, 2022. The First Suit was filed in response to a letter from Zenara dated September 28, 2022 ("Zenara's First Notice Letter"), purporting to be a "Notice of Paragraph IV" for ANDA No. 217760 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 '572 patent, the '351 patent, and the '551 patent. The First Suit included counts for infringement of the '572 patent, the '351 patent, and the '551 patent.

4. Based on information and belief, Zenara is maintaining its certification as to the '572 patent, the '351 patent, and the '551 patent set out in Zenara's First Notice Letter. Thus, Plaintiffs 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 patent is 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 patent. 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, 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.

14. 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.

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

16. 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.

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

18. 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.

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

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

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

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

23. 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.

24. This Court has personal jurisdiction over Zenara Pharma. 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.

25. 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 August 11, 2023). 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.

26. 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.

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

28. 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").

29. 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 Plaintiff in this District.

30. 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.

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

32. 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.

33. 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 '239 patent. 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.

34. 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.

35. 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.

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

37. 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.

38. 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, Plaintiff's 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.

39. 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, Plaintiff's 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.

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

41. 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.

42. 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

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

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

45. 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 Patent

46. 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.

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

48. 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.

Zenara's ANDA No. 217760

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

50. ANDA No. 217760 contains Paragraph IV certifications, alleging that the claims of the '239 patent are invalid, unenforceable, and/or would not be infringed by Zenara's Generic Product.

51. AbbVie received a letter sent by Zenara, dated June 28, 2023, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217760 ("Zenara'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. Zenara's Second 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 '239 patent.

52. Plaintiff commenced this action within 45 days of receiving Zenara's June 28, 2023, Notice Letter.

53. 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 '239 patent expires.

COUNT I
INFRINGEMENT OF THE '239 PATENT BY ZENARA

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

55. 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 '239 patent.

56. 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 '239 patent are purportedly invalid, unenforceable, and/or not infringed.

57. 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 Plaintiff's ORILISSA®.

58. 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 '239 patent, constitutes infringement, either literally or under the doctrine of equivalents.

59. After FDA approval of Zenara's ANDA, Zenara 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 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 '239 patent and any additional periods of exclusivity.

60. 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 '239 patent.

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

62. 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 '239 patent.

63. 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 '239 patent, either literally or under the doctrine of equivalents. Zenara has knowledge and is aware of the '239 patent, as evidenced by Zenara's June 28, 2023, Notice Letter.

64. 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.

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

66. 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.

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

68. Plaintiff will be irreparably harmed if Zenara 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.

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 Zenara has infringed at least one claim of the '239 patent 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 '239 patent;

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

C. 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);

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

F. 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 '239 patent, 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

/s/ Jeremy A. Tigan

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