IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., Plaintiff, v. TEVA PHARMACEUTICALS, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AbbVie Inc. ("AbbVie" or "Plaintiff"), by its attorneys, brings this action against Defendants Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals") and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva"), 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" or "the patent-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 Teva's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiff's commercial pharmaceutical product ORIAHNN® (elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules, submitted under New Drug Application ("NDA") No. 213388), 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 ORIAHNN®. Teva has submitted ANDA No. 217650 ("Teva's ANDA"), which seeks approval to market its generic

version of ORIAHNN®, elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules ("Teva's Generic Product"), prior to the expiration of the '239 patent.

2. Teva 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. 217650 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 '239 patent, or any extensions thereof. Teva 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 Teva's Generic Product prior to the expiration of the '239 patent, or any extensions thereof.

3. Plaintiff AbbVie Inc. previously filed a separate action in this Court against Teva Pharmaceuticals, Inc. and Teva Pharmaceutical Industries Ltd. for patent infringement relating to ANDA No. 217650, which included counts for infringement of U.S. Patent Nos. 10,881,659 ("the '659 patent") and 11,045,470 ("the '470 patent"). *AbbVie Inc. v. Teva Pharmaceuticals, Inc., et al.*, C.A. No. 23-133-RGA (the "First Suit") was filed on February 3, 2023. The First Suit was filed in response to a letter from Teva dated December 21, 2022 ("Teva's First Notice Letter"), purporting to be a "Notice of ANDA No. 217650 . . . With Paragraph IV Certification" for ANDA No. 217650 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 '659 and '470 patents. The First Suit included counts for infringement of the '659 and '470 patents.

4. Based on information and belief, Teva is maintaining its certification as to the '659 and '470 patents set out in Teva's First Notice Letter. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit.

ORIAHNN®

5. ORIAHNN® is a combination of a gonadotropin-releasing hormone (GnRH) receptor antagonist (elagolix sodium), an estrogen (estradiol), and a progestin (norethindrone acetate) indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

6. Elagolix is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of elagolix results in dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone, leading to decreased blood concentrations of the ovarian sex hormones estradiol and progesterone and reduces bleeding associated with uterine fibroids.

7. ORIAHNN® was approved by the FDA on May 29, 2020, pursuant to NDA No. 213388. ORIAHNN® consists of two capsules, one to be taken in the morning and one to be taken in the evening. The morning capsule contains elagolix sodium, estradiol, and norethindrone acetate and the evening capsule contains elagolix sodium.

8. The '239 patent is listed in the Orange Book for ORIAHNN®.

THE PARTIES

9. 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. 213388 for ORIAHNN®. 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.

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

11. 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.

12. 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.

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

14. 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.

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

16. 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.

17. 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 (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules products described in Teva's ANDA throughout the United States, including the State of Delaware.

JURISDICTION AND VENUE

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

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

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

21. 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. 217650.

22. 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.

23. 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.

24. 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 March 29, 2023). 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.

25. 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 March 29, 2023). 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.

26. 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.

27. 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.

28. 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").

29. 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 Plaintiff in this District.

30. On information and belief, the effort to seek approval for ANDA No. 217650 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.

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

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

33. 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. 217650 and in commercializing Teva's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217650 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.

34. On information and belief, Teva Pharmaceuticals and Teva Industries have been, and continue to be, the joint and prime actors for the drafting, submission, request for approval, and maintenance of ANDA No. 217650 with a Paragraph IV certification regarding the '239 patent. On information and belief and as indicated by letter February 13, 2023, sent by Teva to AbbVie 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.

35. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217650, Teva will act in concert to market, distribute, and sell Teva's Generic Product described in ANDA No. 217650 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.

36. On information and belief, if ANDA No. 217650 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.

37. If ANDA No. 217650 is approved, Plaintiff will be harmed by the marketing, distribution, offer for sale, and/or sale of Teva's Generic Product, including in Delaware.

38. 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.*, *Amicus Therapeutics US, LLC v. Teva Pharms. USA, Inc.*, C.A. No. 22-1461-CFC; *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.

39. 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, Plaintiff's 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.

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

41. 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.

42. 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.

FACTUAL BACKGROUND

The NDA

43. AbbVie is the holder of NDA No. 213388 for ORIAHNN® (elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules).

44. The FDA approved NDA No. 213388 on May 29, 2020, for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

45. ORIAHNN® are prescription drugs approved for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Elagolix sodium, estradiol, and norethindrone acetate are the active ingredients in the ORIAHNN®.

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. 213388 for ORIAHNN® (elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules).

Teva's ANDA No. 217650

49. On information and belief, Teva filed ANDA No. 217650 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 (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules dosage forms, which are generic versions of Plaintiff's ORIAHNN®.

50. ANDA No. 217650 contains Paragraph IV certifications, alleging that the claims of the '239 patent are invalid, unenforceable, and/or would not be infringed by Teva's Generic Product.

51. AbbVie Inc. received a letter sent by Teva, dated February 13, 2023, purporting to be a "Notice of ANDA No. 217650 . . . with Paragraph IV Certification" ("Teva'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. Teva's Second Notice Letter notified AbbVie that Teva had filed ANDA No. 217650, seeking approval to market Teva's Generic Product prior to the expiration of the '239 patent.

52. Plaintiff commenced this action within 45 days of receiving Teva's February 13, 2023 Notice Letter.

53. On information and belief, following FDA approval of Teva's ANDA No. 217650, 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 '239 patent expires.

COUNT I
INFRINGEMENT OF THE '239 PATENT BY TEVA

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

55. 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 '239 patent.

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

57. 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 Plaintiff's ORIAHNN®.

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

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

60. 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 '239 patent.

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

62. 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 '239 patent.

63. 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 '239 patent, either literally or under the doctrine of equivalents. Teva has knowledge and is aware of the '239 patent, as evidenced by Teva's February 13, 2023 Notice Letter.

64. 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.

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

66. 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.

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

68. Plaintiff will be irreparably harmed if Teva 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 Teva has infringed at least one claim of the '239 patent through Teva's submission of ANDA No. 217650 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 '239 patent;

B. 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 '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 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);

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

F. 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 '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

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